Eyeing potential US$50 billion market, China gets behind med-tech industry

By Cornelia Zou, Staff Writer

HONG KONG — At Chinese State Council meetings in February, Premier Li Keqiang emphasized the importance of innovation and upgrades to the health care sector, once again highlighting the importance of the pharmaceutical and medical device industries for China’s next phase of development. Even as China’s economy and international trade slows down, the med-tech sector continues to surge forward.

Exports of medical devices reached US$21.2 billion in 2015, a 5.7 percent increase, while imports hit US$17.3 billion in 2015, 9.8 percent higher year on year.

“Last year, Chinese medical device companies did a pretty good job, the import-export volume grew 7.5 percent to US$38.5 billion,” Xu Ming, vice president of the

FDA says pivotal study for Diam may have introduced bias

By Mark McCarty, Regulatory Editor

The FDA hearing for the Diam spinal stabilization system may or may not go the way of Medtronic plc’s Sofamor Danek unit, but the agency’s meeting summary suggests the sponsor had some credibility issues to address. The FDA summary stated that the agency’s reviewers had concerns “that the design of the study, and the way in which the data was collected and analyzed, may

DEVICES MUST RETAIN CLASS III STATUS

FDA sets PMA, PDP submission deadline for MoM hip implants

By Richie Crider, Staff Writer

Manufacturers of metal-on-metal (MoM) semi-constrained total hip replacement prostheses with or without a cemented acetabular component have until May 18 to submit either a premarket approval application (PMA) or a notice of completion of a product development

BRINGING TECHNOLOGY TO U.S. MARKET

Bruin Biometrics scores contract with Virgin Care for SEM Scanner

By Omar Ford, Staff Writer

Med-tech companies often have two challenges for a new device – gaining approval and making sure the technology is adopted. Bruin Biometrics LLC, a company spun off from the University of California Los Angeles, said it is making significant progress on both fronts. The company, which already has CE mark approval for the subepidermal moisture

NEWCO NEWS

RDD seeks patient-friendly solution to uncomfortable problem

By Marie Powers, News Editor

Individuals with complete spinal cord injuries face a lifetime of complications, not the least of which is fecal incontinence. But those patients – approximately 250,000 in the U.S. who live with the condition, four out of five of them men – represent just the tip of the iceberg for those with rectal diseases,

NEUROLOGY EXTRA

Senior Staff Writer Amanda Pedersen on one of med-tech’s key sectors

Medical Device Daily presents Patent Highlights, an excerpt of the most important med-tech patents from this week’s Cortellis Patents Gazette. See the attachment at the end of this edition.

See China, page 4
See FDA, page 6
SeeRDD, page 7
See Bruin, page 8
See Regulatory, page 5
See this week’s Monday Special
**OTHER NEWS TO NOTE**

**Chembio Diagnostics Inc.** was awarded a $550,000 catalyst grant from philanthropist and entrepreneur Paul Allen to start developing a cost-effective point-of-care diagnostic tests to identify Zika virus and related febrile illnesses. The grant is managed by Allen’s company, Vulcan Inc. and the funds come from the Paul G. Allen Family Foundation. The Medford, N.Y. company said it is in discussions with health and government organizations to secure additional funding to support accelerated product development, as well as clinical trial and regulatory approval for its Zika products. Chembio said it will use its Dual Path Platform (DPP) technology to develop a stand-alone POC assay to detect Zika virus and a multiplex POC assay to simultaneously detect Zika, Dengue and Chikungunya viruses. In addition, Chembio will add Zika to the POC DPP fever panel that is currently under development through a separate grant from the Paul G. Allen Ebola program. That assay is designed to detect viruses with a single drop of blood from the fingertip.

The U.S. Department of Justice is set to collect US$23 million from hospitals that allegedly billed Medicare incorrectly for ICDs. The fines are spread across 51 hospitals in 15 states. But “claims resolved by these settlements are allegations only and there has been no determination of liability,” the DOJ said in a statement. The agency has already settled with 457 hospitals for more than $250 million over related claims. The hospitals in question from hospitals that allegedly billed Medicare incorrectly for ICDs.

**PRODUCT BRIEFS**

Wound Management Technologies Inc., of Addison, Texas, said its Resorbable Orthopedic Products (ROP) subsidiary has received FDA 510(k) clearance for Hemaquell resorbable bone wax. Hemaquell is a water soluble material that is used as a tamponade to control bleeding from bone surfaces. It is based on the multi-faceted patent that the company acquired in 2009. Hemaquell will be delivered in an applicator that allows surgeons to directly apply the waxy product on bleeding bones. Hemaquell bone hemostasis material is completely resorbed between 2 and 7 days and does not delay healing of bone injury.

Bridgewater, N.J.-based **Nipro North America**, a division of **Nipro Medical Corp.**, reported the launch of the Cronus HP high-pressure, 0.035” over-the-wire (OTW) percutaneous transluminal angioplasty (PTA) balloon catheter. Cronus HP is indicated for percutaneous transluminal angioplasty in the femoral, popliteal, iliac and renal arteries and for the treatment of obstructive lesions in native or synthetic arteriovenous dialysis fistulae. Cronus HP is intended to treat AVF stenoses ranging from simple, focal, venous outflow strictures to more complex juxta-anastomotic obstructions in early fistula failures.///

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## MDD Stock Report for Public Med-Tech Companies

### 10 Biggest U.S. Winners for the Week

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<thead>
<tr>
<th>By Percent</th>
<th>By Dollars</th>
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<td>Penumbra</td>
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<td>Abiomed</td>
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<td>Stereotaxis</td>
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<td>Inogen</td>
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### 10 Biggest U.S. Losers for the Week

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<td>Affymetrix</td>
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### Notes

Trading volumes for Nasdaq, Amex and NYSE are recorded as the total number of shares traded (in thousands) on a weekly basis (cumulative Monday through Friday); the weekly and YTD % changes are from IPO completion, where applicable.

**Average Percent Change Week:** +3.62%
- Range: +15.64% to +16.58%; Number Of Companies: 76
- (not market weighted)

**Average Percent Change YTD:** -13.09%
- Range: -46.10% to +54.03%; Number Of Companies: 76
- (not market weighted)
China

Continued from page 1

China Chamber of Commerce for Import & Export of Medicine & Health Products (CCCMHPIE), told Medical Device Daily. According to China Customs data, the total import and export value of China's medicines and health care products hit a new record of US$102.6 billion in 2015, up 4.73 percent year-on-year. Exports reached US$55.4 billion, up 2.7 percent, while imports hit US$46.2 billion, also rising 2.7 percent. All told, the country's foreign trade surplus was US$10.2 billion, down 13.99 percent.

“The total volume of exports or imports [of medical devices] have all hit record highs,” said Xu. “Among all kinds of medical devices, hospital diagnostics and treatment devices ranked the first in terms of export volume.”

Xu said that the export volume of this kind of device reached US$9.7 billion last year, 7.9 percent more than in 2014. Imports of hospital diagnostics and treatment devices was also the largest among other segments, which grew 9.3 percent to US$12.5 billion last year.

“Compared with 2014, import and export growth has slowed down,” said Xu. “But against the backdrop of the overall sluggish growth, the health care sector is actually doing well.”

What needs to be highlighted is that Chinese medical device makers are shifting from low value-added consumables to high value-added finished products even though the high-end segment is still dominated by foreign companies.

“The export of middle to large medical devices has grown,” said Xu. “For example, the export of device accessories has declined 0.5 percent last year while the sector grew 5.7 percent.”

As with other sectors, the med-tech space is running up against a downturn in the global economy, with weak global demand, exchange rate fluctuations and higher environmental controls. At the same time, China's medicines and health care products trade has entered into a slower growth phase. CCCMHPIE predicts that trade will grow between 3 percent and 5 percent in 2016.

Even at the slower rate, China's industry should emerge as a world-class giant.

Research and consulting firm Globaldata said that the Chinese medical device market is set to rise from US$27.7 billion in 2014 to US$50.8 billion by 2020, expanding at a strong compound annual growth rate of 10.6 percent.

In a new report, Globaldata said growth in the country’s medical device market will be driven by factors that include the increasing prevalence of metabolic syndromes and chronic diseases, an aging population and government investment.

COMPANIES TO BENEFIT FROM CHINA’S BURGEONING HEALTH CARE NEEDS

Globaldata believes that the leading device multinational companies in China who will benefit are Siemens Healthcare GmbH and GE Healthcare, who were among the top exporters in terms of value last year, as well as Philips Healthcare, Medtronic and F. Hoffman-La Roche.

“The dominant player in terms of revenue in China is Siemens, which has a best-in-class portfolio of ultrasound and medical imaging solutions,” said Adam Dion, senior industry analyst at Globaldata in a note. “As an emerging market, China offers Siemens a significant opportunity for growth, particularly in the diagnostics space. Factors driving this growth include the increasingly elderly population, increased awareness of medical conditions, the availability of treatment options, and higher incomes.”

China's diagnostics market is projected to experience the biggest growth of all segments, rising 13.8 percent every year from US$9.3 billion in 2014 to US$20.1 billion in 2020.

“The rate of use of in vitro diagnostics (IVD) products for diagnosis is currently low in China but is growing steadily,” said Dion. “The benefits of early diagnosis are expected to drive adoption rates for IVD products, which will provide an opportunity for multinational players in China.”

The structure of China’s medical device industry has changed quite a bit in the past few years as big companies are getting even bigger while small companies are acquired or merged.

According to the CFDA’s annual administrative statistics report released this month, China had 14,151 medical device companies as of the end of November 2015. Among them, 5,080 are class I device manufacturers, 9,517 are in the class II device business category and 2,614 are focused on class III devices. Although the overall number of companies has increased, there are fewer class III medical device companies. Another State Council document released at the beginning of this year eliminated the government’s reviewing process of listed companies’ M&A activities. This could also be good news for listed medical device companies looking to boost their scale. //

FINANCINGS

Great Basin Scientific Inc., of Salt Lake City, priced a public offering of 39.2 million units at 16 cents a unit, with gross proceeds expected to be about US$6.3 million (net proceeds of US$5.6 million). Each unit will consist of one share of common stock and 1.5 series E warrants. Each whole series E warrant will be worth one share of common stock, subject to adjustment, for 25 cents a share for five years following the date they first become exercisable. The series E warrants will not be exercisable until at least one year from the date of issuance and exercise of the series E warrants is subject to certain stockholder approval requirements. Roth Capital Partners served as the sole placement agent for the offering. The offering is expected to close Wednesday. Great Basin intends to use the proceeds for research and development, sales and marketing expenses, to support the manufacture of additional analyzers, to expand its manufacturing capacity and for general corporate purposes including working capital. //

Regulatory
Continued from page 1

have resulted in inaccuracies and introduced bias.”

The agency stated that it had granted the IDE for the Diam in June 2006, and that reviewers at the Office of Device Evaluation had expressed concerns about the design of the study at that time. Among the concerns said to have been voiced were the study population, the selection of a control group and the evaluation time points for determining overall success.

The device’s history reaches back to 1997, when a somewhat different design was at play, and the Diam has been available in Europe since no later than 2007 (some sources peg global experience at more than 25,000 implants). The FDA meeting notes stated that Medtronic had proposed the trial would examine the device’s use in patients with “low back pain” secondary to lumbar degenerative disc disease (DDD), with a proposed use as an alternative to standard of care when fusion or disc replacement is not yet indicated.

The agency had argued that low back pain “is a symptom and not a specific diagnosis,” and that there is as yet no evidence-based clinical classification scheme that splits low back pain into mild, moderate and severe stages along with treatment recommendations for each stage. The FDA stated that the pivotal study was designed as a superiority study matching the Diam against non-surgical treatment for those experiencing moderate pain at lumbar levels 2-5 for evaluation at 12 months. The 38-site study would randomize patients at a 2:1 ratio to the study article and non-surgical care, with a proposed enrollment of 316 subjects.

The FDA document said that one consideration was the heterogeneity of the study population, said to have included those with herniated discs, spinal stenosis and facet joint degeneration, among others. Consequently, the FDA said it did not accept the sponsor’s argument that data from sub-populations were poolable in a post-hoc analysis.

The agency cited as problematic the enrollment of patients with an Oswestry Disability Index score of 49 or more despite that the ODI index characterizes such patients as suffering from severe pain. Some enrollees subsequently underwent surgery at adjacent or multiple levels of the spine, which the FDA argued was an indication that some subjects “may have had multi-level disease upon entry into the clinical trial.”

Another sore spot for FDA was the allegation that many data points were not recorded during the course of the study, but rather were documented in “post hoc review[s] of medical records, operative reports, and radiographs by the sponsor.” Among these were identification of additional surgical procedures and characterization of spinous process fractures.

The sponsor’s summary said that a 12-month interim analysis of 150 patients demonstrated statistical superiority in a composite primary endpoint that captured both safety and efficacy scores. A subsequent analysis of 181 subjects with the study article and another 101 controls “demonstrated similar results,” the company said, although controls were allowed to cross over to the study article at six months. The company added that the post-hoc analysis was conducted at the FDA’s behest.

Medtronic indicated that the interim analysis was driven by a slower-than-expected rate of enrollment for what the FDA said is a first-of-a-kind device. The company’s meeting summary observed that the device, which is surgically inserted between the spinous processes of adjacent vertebrae, absorbs axial spinal pressure, thus relieving some pressure from the posterior portions of the disc along with the annulus and facet joints. The device is further said to re-tension the supraspinous ligament “and other ligamentous structures.”

The interim analysis was part of a sponsor-requested change to the protocol, which the FDA approved in July 2013. The protocol was amended to stipulate that enrollees into the control arm undergo patient education and only one or more of four non-operative therapies, whereas the original study protocol apparently required that controls undergo all four non-surgical options, a list that included physical therapy, spinal injections and medication. Other adjustments to the study protocol at this date included changes to disc height loss at the index level compared to adjacent levels, and the company stated that 59 controls had crossed over to the study’s device arm.

*Medical Device Daily* will cover the outcome of the advisory hearing in a later issue.

**PENTAX Wins FDA Nod for ‘Scope Reprocessing**

Add Tokyo-based Pentax Medical to the list of makers of duodenoscopes that have won an FDA approval for an update to the cleaning instructions for the device, in this instance for the Pentax ED-3490TK video duodenoscope. The FDA announcement said the company had initially filed the updated cleaning instructions with the agency in October 2015, and that Pentax had updated the filing in January, at which point the FDA gave the company an affirmative nod.

The announcement stated that the new instructions include updates on pre-cleaning instructions, specifically addressing “flushing of the elevator mechanism with detergent,” along with manual cleaning instructions that specify proprietary Pentax brushes. Pentax removed ethylene oxide as a method for sterilization, but added the use of the System E-1, made by Steris of Mentor, Ohio, as a liquid sterilization method.

**FDA Seeks Industry Reps for ADCOMMS**

The FDA announced it is seeking new advisory committee members to serve as representatives of industry for several advisory committees, although there are apparently no openings on the circulatory systems advisory committee. Those in the field of diagnostics may see some opportunity, however, as there is an opening in both the microbiology and the molecular and clinical genetics committees.

Interested parties may self nominate and can contact FDA’s Margaret Ames at margaret.ames@fda.hhs.gov by March 21.
FDA
Continued from page 1

protocol (PDP) to the FDA for review and approval or the agency will deem the device adulterated.

After years of monitoring the overall performance of these class III devices, FDA issued a final rule on Feb. 18 making it mandatory that manufacturers submit either a PMA or PDP. However, the rule focuses solely on PMA submissions since the option of submitting a notice of completion of a PDP has rarely been used, the agency said.

“Given the known risks, the FDA believes that there is insufficient evidence and information to conclude that general controls in combination with special controls would provide reasonable assurance of the safety and effectiveness of these devices,” the agency said. “The agency has determined that these devices should remain class III (higher risk) devices and PMA applications must be filed with the agency by May 18, 2016, if a manufacturer wants to continue marketing their MoM total hip replacement devices and/or market new MoM total hip replacement devices.”

According to the rule, the PMA must include any risks that are known or should be reasonably known to the applicant. PMA filings must also include full reports of all nonclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

The notice goes on to state that manufacturers of MoM implants may continue to market the device while their application is under review at the agency. If the FDA later denies the application, however, the device will be deemed adulterated and subject to enforcement action.

FDA said it intends to review the PMAs within 180 days and PDP notices within 90 days of submission. However, FDA regulations prevent the agency from entering into any agreement to extend the review period beyond 180 days unless the agency finds that “the continued availability of the device is necessary for the public health.”

FDA PRODS SURE GENOMICS FOR APPROVAL NUMBER

In a letter dated Feb. 16, the FDA asked Sure Genomics of Sandy, Utah, to justify taking orders for its SureDNA test without first obtaining FDA clearance of the device.

“We have conducted a review of our files, and have been unable to identify any FDA clearance number for the SureDNA test,” the letter said. “We request that you provide us with the FDA clearance number for the SureDNA test. If you do not believe that you are required to obtain FDA clearance for the Sure DNA test, please provide us with the basis for that determination.”

The test is intended to collect saliva samples for DNA sequencing and for the reporting of patient information, such as disease risks and the likelihood of drug reactions.

A spokesperson from Sure Genomics told Medical Device Daily that the company has been working closely with the agency since before it launched the product and will continue to work with the agency to resolve the issue and become completely complaint.

The agency also inked a Feb. 17 letter to Solopap International, Ltd. Of Henderson, Nev., for marketing of the company’s tests for human papillomavirus and Pap, a test offering dubbed the Home HPV&PAP test. The agency said that a review of its files disclosed no approval number for the test, and asked for an explanation for why the company might believe the test calls for no approval.

The letter requested a sample lab report providing test results to physicians, and that the company respond to the letter within 15 business days of receipt.

WORKSHOPS PLANNED ON WARFARIN THERAPY, NEW EVIDENCE SYSTEM FOR DEVICES

FDA is planning to host two workshops in March, one on point-of-care (POC) prothrombin time/international ratio devices for monitoring warfarin therapy and another on building a national evaluation system for medical devices.

The agency is hosting the March 18 workshop on monitoring warfarin therapy to discuss and receive input from stakeholders regarding approaches to the analytical and clinical validation of POC prothrombin time/international normalized ratio (PT/INR) in vitro diagnostic (IVD) devices. The goal is to improve clinical management of warfarin therapy, and the FDA plans to outline its process for facilitating the safe and effective development of the devices during the workshop.

A key outcome for the agency will be to identify and address potential challenges with regulating the tests. The workshop initially was scheduled for Jan. 25, but was canceled due to inclement weather. Industry will have until April 18 to submit their comments following the workshop.

The workshop on building a national evaluation system for medical devices will be held on March 24 in conjunction with the University of Maryland Center of Excellence in Regulatory Science and Innovation. The purpose of this workshop is to discuss the scientific progress being made to harness evidence generated from the real-world use of medical devices to improve device safety and effectiveness.

According to the agency, a national evaluation system would leverage that evidence to help FDA more efficiently strike the right balance between premarket and post-market data collection, facilitate access to medical devices, and more quickly and robustly identify safety signals that may arise in the post-market period.

“The promise of using real-world evidence to promote the safety and effectiveness of medical devices can only be achieved through robust public-private partnerships and new approaches to informatics, epidemiology, biostatistics, and health care data systems integration,” the agency said in the notice.

Comments can be submitted on both workshops by referencing docket number FDA-2015-N-4462 (warfarin) and docket number FDA-2016-N-0382 (national evaluation system) at regulations.gov.
RDD
Continued from page 1

including anal fissures and fistulas.

Nearly 8 percent of non-institutionalized adults in the U.S., or some 20 million individuals, suffer from fecal incontinence, or loss of bowel control. The condition, which results from damaged or weakened anal sphincter muscles, can occur at any age and often leads to placement in a long-term care facility because family members cannot adequately manage their loved one’s condition at home.

Unlike the need, treatment options are sparse. No prescription drugs are approved in the U.S. for the condition.

RDD Pharma Inc., of Tel Aviv, saw that imbalance as a niche opportunity.

Founded in 2008 in a life sciences incubator in Israel’s Office of the Chief Scientist, RDD is focused on fast-track development and commercialization of therapeutics for anorectal diseases and gastrointestinal disorders, using the 505(b)(2) pathway. Based on its early progress, in 2012 the company attracted outside funding from its main backer, Orbimed Advisors, and smaller stakes from Israeli seed investor Ofakim Hi-Tech Ventures and the German investment fund Corporate Finance Holding GmbH.

The company’s lead candidate, RDD-1219 (nifedipine), is a calcium channel blocker formulated as a “capository” – a combination suppository and capsule – to treat pain associated with anal fissure. RDD-1219 is expected to start a phase III study in Europe in the first quarter, followed by a second phase III in the U.S. that also expects to begin enrolling patients this year. The drug is designed to normalize internal anal sphincter pressure, leading to a healthier blood supply to stimulate healing of the area. In two phase II studies that enrolled 54 patients in total, RDD-1219 demonstrated superior pain relief to Rectogesic, a glyceryl trinitrate ointment approved in the U.K., without that product’s side effect profile, which includes headaches in a majority of users.

RDD – an acronym for rectal drug delivery – also is preparing to advance RDD-0315 (phenylephrine), an alpha agonist also formulated as a capository, into a phase IIb study this year in fecal incontinence. The company reported in January that a pilot study of the compound, which sends a signal to the anal sphincter to contract, met its efficacy endpoint. The double-blind, crossover phase IIa study, conducted in 19 patients with spinal cord injury, showed a statistically significant 25 percent reduction in the number of fecal incontinence episodes at eight and 12 hours following administration in the treatment arm compared to placebo.

RDD-0315 also was well tolerated by patients and met safety goals. No systemic absorption was observed, with plasma levels of RDD-0315 below detectable limits.

INDICATIONS ‘DON’T NEED A LARGE COMMERCIAL ORGANIZATION’

Jason Laufer joined RDD two years ago as CEO, attracted by the urgent need to treat a sensitive medical condition that was receiving almost no attention from the pharma world.

“Although many companies are in the gastrointestinal space, no single company is focused on the last stop of the gastrointestinal tract, which is the anal-rectal region,” Laufer told Medical Device Daily. “That’s for a variety of reasons, not the least of which is that people who suffer from anal-rectal diseases don’t talk about them.”

See RDD, page 9

CLEARLY CORTELLIS

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Bruin
Continued from page 1

(SEM) scanner, a device for pressure ulcer detection and prevention, is vying for FDA approval and has secured a major contract for the distribution of the technology. Bruin Biometrics revealed a supply agreement with Virgin Care, an independent provider to the National Health Service of England. Virgin Care picked up the SEM Scanner from the Los Angeles-based company following a successful six-month pilot.

“[Virgin Care] took the view that they were interested in the product but they wanted to prove its use for themselves,” Martin Burns CEO of Bruin Biometrics, told Medical Device Daily. “They wanted to see if they could actually get the results that we were suggesting they could get. What they found during the use of our product was they were able to give their nurses information they never had before.”

As a result, Virgin Care reduced pressure ulcers – a preventable patient safety issue costing the NHS more than £2 billion per year – by about 95 percent, to nearly zero, with the SEM scanner. The device is a hand-held point-of-care diagnostic device that measures increased fluid content within the underlying tissue of skin known SEM.

SEM – sometimes referred to as interstitial fluid – is associated with localized edema in the inflammatory phase. This phase is the body’s first response to tissue damage and is indicative of impending skin damage and pressure ulcer formation.

“We’re doing a phased deployment, so that over the next couple of months, all being well, this will be basically be [Virgin Care’s] standard of care for pressure ulcer detection across their entire network,” Burns said. “For [Bruin Biometrics] that’s a very meaningful transaction.”

Burns would not disclose financial terms of the deal but said it was one of the largest Bruin Biometrics, which has been in existence since 2009, has seen. Virgin Care will acquire up to 100 SEM scanners. He noted that Virgin Care has also agreed to do a number of peer-reviewed publications with on the SEM scanner.

The deal with Virgin Care comes after Bruin Biometrics completed a US$9 million series A funding round in January. The round was financed by new and existing investors. Proceeds from the financing will be used to accelerate the commercialization of the SEM scanner, a hand-held device for detecting early-stage pressure ulcers. In February 2014, the company revealed it completed a US$10.7 million funding round. The money helped with the European roll out of the device. In addition the 2014 funding was used to help continue research and development on the company’s product pipeline.

Bruin Biometrics is pursuing a de novo review to gain FDA approval for the scanner. It said it could launch the product in early 2017.

There is a significant market for the device in the U.S. It is estimated there are about 2.5 million patients each year that are affected by pressure ulcers and the prevalence rate peaks around 25 percent in elderly patients. About 60,000 people die from these ulcers each year due to complications, which include sepsis. Part of the reason for interest in the technology is due to policy reforms in health care, which not only defined never events – serious medical incidents that are avoidable and should never occur – but also introduced penalties for these events and created Accountable Care Organizations. The result is increased pressure on hospitals and health care facilities to prevent these incidents from occurring.

“It’s a de novo device,” Burns said. “We met with FDA in November and had a great meeting with the agency. Our approach to dealing with FDA and all of our regulators is that we go out of our way to be collaborative and transparent.”
RDD

Continued from page 7

Without discounting the seriousness of rotator cuff surgery, stent placements and chemotherapy treatments – common topics of public conversation – Laufer maintained that anorectal disorders such as anal fissure and fecal incontinence are "highly" prevalent and debilitating.

"This was an opportunity to be a sort of pioneer," said Laufer, who started his career nearly three decades ago in clinical and regulatory affairs at New York-based Pfizer Inc. and subsequently held executive roles in specialty pharma and medtech.

The potential market opportunity isn't exactly trivial, either. The U.S. market for anal fissure treatment is estimated at $600 million, with the fecal incontinence market projected to be approximately $3 billion.

The company's capository formulation is designed to provide the exact amount of drug directly to the affected area with maximum patient compliance. Regulators have guided the company that the drug/device combo will be regulated as a drug, but the complete package is key to a user-friendly solution.

"Without the delivery system, patients will not consistently administer the drug," Laufer said. "It's an innovative way to treat a disease that occurs in a very problematic place."

And that's not just the unpleasantness factor. The anorectal region has unique physiological challenges, including high temperature and humidity, frequent abrasion and absorptive capacities, he pointed out.

RDD's candidates also are formulated for extended release, typically giving patients four to five hours of freedom to perform a variety of common activities, including work, shopping, medical appointments and social engagements, according to Laufer.

If the RDD-1219 phase III program succeeds in anal fissure, RDD could file its marketing authorization application in the EU next year, followed by a new drug application to the FDA in 2018. EU authorities indicated they will accept a single phase III study that enrolls 300 patients, while the FDA is looking for data on 500 patients, Laufer said, so the company will enroll another 200 in the second phase III.

RDD holds patents on two additional indications – pruritus ani, or chronic anal itching, and cancer treatment-related radiation colitis – that extend its "innovation bin," Laufer added. And the company has kept its overhead to a minimum, with the equivalent of just four full-time equivalents.

With major milestones looming, RDD is in the process of raising a $15 million series B round that Orbimed already agreed to support. The funds will allow the company to move RDD-1219 to registration in anal fissure in the EU and U.S. and to complete the RDD-0315 phase IIb program in fecal incontinence. At the point of commercialization, the company expects to have multiple options.

"The nice thing about both indications is that you don't need a large commercial organization to properly detail it," Laufer said, suggesting the company could hire its own sales team. "But we also believe the appetite by established companies for products such as these, which address unmet medical needs, will lead specialty phamas and other commercial partners to knock on our door."

APPOINTMENTS AND ADVANCEMENTS

Advanced Medical Technology Association's (AdvaMed) board said that Scott Whitaker will be its next president/CEO April 4, 2016. Whitaker joins AdvaMed having served most recently as COO of the Biotechnology Innovation Organization (BIO). As BIO's COO, Whitaker managed all aspects of the organization's day-to-day operations, including advocacy, policy, communications and non-dues revenue business. As president of the BIO International Convention, Whitaker oversaw the largest gathering of the biotechnology industry. Prior to joining BIO, Whitaker served in key leadership roles at the Department of Health and Human Services, including as chief of staff and assistant secretary for legislation. Whitaker is due to replace Steve Ubl, who left last year to take the reins at Phrma.

Milestone Scientific Inc., of Livingston, N.J., a medical R&D company that designs, patents, incubates and commercializes a portfolio of injection technologies, said it has formed a global advisory board to aid in the commercialization of its medical instruments and also appointed industry veteran Bob Miglani as its inaugural member. Miglani has been with Pfizer Inc. for 23 years, where he held various senior sales, pricing, reimbursement, corporate affairs, as well as market access roles and was responsible for managing projects and strategies in multiple countries including the U.S., Europe and India.

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Nanoparticles show early promise after bleeding stroke

Nanoparticles from ceria, a rare earth metal, might lessen inflammation in the brain after a bleeding stroke, according to research presented at the American Stroke Association’s International Stroke Conference 2016. Previous studies have shown that ceria nanoparticles have strong antioxidant properties as well as anti-inflammatory effects. This study, from South Korean researchers, investigated whether the nanoparticles could reduce inflammation that occurs just after an intracerebral hemorrhage. The researchers studied a type of white blood cell called macrophages taken from the brains of rats and applied ceria nanoparticles to them. Compared with untreated macrophages, the macrophages treated with the nanoparticles secreted fewer inflammation-promoting chemicals. In a second experiment, they injected ceria nanoparticles in 10 rats with brain bleeds. Compared with 10 untreated rats, the treated rats had less damage at the stroke site and less water accumulation, suggesting less inflammation in the area of the stroke, researchers said.

Exosomes may enhance brain recovery after stroke

Small vesicles secreted by cells help facilitate growth and development of blood vessels and neurons in the brain following a stroke, according to a new study presented at the American Stroke Association’s International Stroke Conference 2016. Researchers from Detroit and China suspected that exosomes, which are secreted from cells and play a role in communication from one cell to another, might facilitate the growth and development of blood vessels and of nerve cells or neurons. The team tested the hypothesis by isolating brain cells from healthy rats and rats whose brains had been damaged by a blood vessel blockage. Two types of cells were isolated: cerebral endothelial cells (which line blood vessels in the brain) and neural progenitor cells (which can differentiate into other types of brain cells). Exosomes were harvested from those cells and tagged with fluorescent particles to help the researchers determine if cells successfully internalized the exosomes. The team first studied exosomes from endothelial cells engulfed in neural progenitor cells. They found that in rats with brain damage from a stroke, neural cells containing exosomes from endothelial cells multiplied more rapidly and differentiated more distinctly than neural cells with comparable exosomes from healthy rats. Findings were similar when the experiment was conducted in reverse, applying exosomes from neural progenitor cells to endothelial cells: The exosomes from rats with the damaged brains more actively promoted growth and development of blood vessels, compared to the exosomes from healthy rats. The results suggest that exosomes may be useful in enhancing brain recovery after stroke, researchers said.

Study may explain drug resistance in aggressive brain tumors

Scientists may have found an explanation for why current drug treatments fail against glioblastoma multiforme (GBM), one of the most aggressive brain tumors known. The results were published in two articles in PLOS ONE magazine. The researchers, with participation of the University of Granada (UGR), have proven that proteoglycans (the cells’ structural elements), called decorin (DCN) and lumican (LUM), could be decisive in the behavior and development of a resistance to the drugs used for treating GBM, such as temozolamide. They reported that the inhibition of the transcription of some of the sub-units belonging to the mismatch-repair (MMR) complex, a system that analyzes and repairs DNA, could be responsible of the failure of current therapies against this kind of tumor. The researchers said the discovery could lead to new resistance markers in GBM as well as new therapeutic strategies which avoid the resistance of drugs that GBMs possess. The team included researchers from the UGR Institute of Biopathology and Regenerative Medicine and from the Biosanitary Institute of Granada in collaboration with the Bellvitge Biomedical Research Institute and the National Institute of Biosystems and Biosystems and the University of Sassari.

Brains are more adaptable than previously thought

Montreal researchers said star-shaped brain cells, known as astrocytes, which play fundamental roles in nearly all aspects of brain function, could be adjusted by neurons in response to injury and disease. The discovery shows that the brain has a far greater ability to adapt and respond to changes than previously believed, which could have significant implications on epilepsy, movement disorders and psychiatric and neurodegenerative diseases, according to the team from the Research Institute of the McGill University Health Centre. Their work was published in the journal Science. The researchers said it was previously believed that astrocytes acquired their properties during the development of the brain and then they were hardwired in their roles. But the team found that astrocytes are actually incredibly greater ability to adapt and respond to changes than previously thought
MEDICAL DEVICE DAILY’S PATENT HIGHLIGHTS

FROM CORTELLIS’ PATENTS GAZETTE
WEEK 06
DEVICES AND EQUIPMENT

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The Patents Gazette provides snapshot analysis and indexing of pharmaceutically relevant patenting within days of its publication by patent offices. Primarily focusing on material from the main three patents offices (ie the EPO, USPTO, and WIPO), it provides brief descriptions of a patent’s content and seeks to link it to both prior patenting of relevance and to any commercial activity pertinent to the technology being described.

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Assignee: F Hoffmann-La Roche AG; Roche Diagnostics GmbH; Roche Diabetes Care Inc
Inventors: Kube, Oliver; Orth, Michael; Walter, Helmut
IPC Codes: A61B 17/34; A61B 5/145; A61B 5/00
Publication Date: 10-Feb-2016 (also published as US20160038180-A1, 11-Feb-2016)
Earliest Priority Details: EP2014179911, 05-Aug-2014

An apparatus for the insertion of a medical sensor or probe for in vivo monitoring of an analyte such as glucose, particularly for inserting a transcutaneous analyte sensor into the subcutaneous region. The medical applicator has means lifting skin and subcutaneous tissue away from the underlying muscle tissue for and towards the insertion needle for puncturing and insertion of the sensor. This is achieved by applying underpressure to the cavity for taking, through the orifice, an adjacent portion of the skin/tissue into the cavity by suction. The invention may enable single-handed operation of the device by a user without the need for operation by professional health personnel. Suction based operation may have the advantage of equilibrated and widely-spread force application and may help avoiding hematoma and unintentional injury of skin and/or subcutaneous tissue.

Published alongside WO2016020370 describing methods and devices with sterilized portions to be implanted within the body of the user and/or that are in contact with the body of the user. For previous patenting featuring Kube and Walter describing a medical sensor assembly comprising a flexible plaster adapted for adhesion onto the skin of a patient, see WO2016016217 published one week earlier.

The invention would seemingly suggest that Roche is seeking to develop alternatives to the technologies traditionally employed within its glucose sensing products, such as its Accu-Chek® FastClix lancing device that is used in tandem with its range of Accu-Chek® blood glucose meters.
Methods and devices (112) with sterilized portions (130) to be implanted within the body of the user and/or that are in contact with the body of the user. The device may have an electrochemical sensor for detecting analytes in body fluids are disclosed as including glucose, cholesterol, triglycerides and lactate and it is discussed that the invention has possible applications in the field of diabetes care, both in home monitoring and in hospital applications. The device’s housing (116) is configured to provide a sterile packaging such that the implantable portion (130) is sealed against the surrounding environment. The invention may allow a method for producing a medical device to be performed without sterilizing the electronic device. It is stated that this waiver of sterilizing the electronic device may yield a reduction of production costs and logistical advantages.

Published alongside EP2982302 from a different team at Roche, describing an apparatus for the insertion of a medical sensor or probe for in vivo monitoring. For prior Roche patenting describing a medical sensor assembly comprising a flexible plaster adapted for adhesion onto the skin of a patient, see WO2016016217 published one week earlier.

Assignee: GenCell Biosystems Ltd
Inventors: Barrett, Brian; Chawke, Brian; Curran, Kieran; Daly, John; Sirr, Noel
IPC Codes: B01J 19/00
Publication Date: 11-Feb-2016
Earliest Priority Details: US201432899, 04-Aug-2014

Bench-top nucleic acid library preparation device comprising a thermal chip to receive a composite liquid cell (CLC) reaction cartridge, a consumable reagent location to receive a CLC nucleic acid library preparation reagent cartridge, a sample location to receive a CLC sample cartridge and a robotically controlled liquid handler to transfer liquids. Also, describes a magnetic nucleic acid library purification system. Provides precise biochemical reactions in small working volumes and avoids the step of nucleic acid preparation prior to sequencing. Published alongside WO2016020838 describing other aspects of the genomic analysis device. Follows on from the team’s claims for a CLC mediated nucleic acid library preparation device in WO2015120398.

In October 2014, Becton Dickinson and Company acquired GenCell Biosystems to form BD GenCell Biosystems to develop into the next generation sequencing market with its BD CLiC™ product, ie a transformational benchtop NGS library prep technology that is powered by GenCell's CLC technology (imagery of which was included within this application). One of the inventors named here, Kieran Curran, was the founder and CEO of GenCell Biosystems and subsequently Director at BD GenCell Biosystems, prior to leaving in December 2015 to return as Director of Curran Scientific (from which GenCell Biosystems had originally been spun off in early 2011).

With an experienced design and manufacturing team working from development laboratories in Limerick-Ireland, Curran Scientific describes itself as providing and developing state-of-the-art fluid handling technologies for applications in biotechnology, medical devices and electronics.
**WO2016020775-A1: “Diagnostic, prognostic, and analytical system.”**

Assignee: Kimiya Pty Ltd

Inventors: Alavioon, Sara; Azimi, Mehdi; Vonwiller, Simone Charlotte; Worsman, Matthew Taylor

IPC Codes: G01N 21/75; G01N 33/487; G01N 21/00; G01N 33/48; G01N 21/85; G01N 33/574; G01N 21/01

Publication Date: 11-Feb-2016 (shares priority details with copublished WO2016019428-A1)

Earliest Priority Details: US201434815, 08-Aug-2014

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**Figure 1**

**Figure 5**

Assay device for analyzing a liquid sample (nipple aspirate fluid), comprising an inlet and disposable parts with a reaction chamber and an analysis module with a photosensor, which is adapted with a syringe pump with barrel, a heater, and a sensor configured to detect fluids within the device and an analysis chip. The device is configured to amplify nucleic acids with an isothermal amplification reaction and generates signals indicative of the presence or absence of an analyte. The invention is said to offer a range of nm to mm scale features that enables inexpensive, reliable, quick, convenient, and widely accessible point-of-care systems for identifying and diagnosing breast cancer. Examples within the disclosure report methods of analyzing ESR1, ESR2 and TP53 genes for mutations indicative of breast cancer.

Along with concurrently published WO2016019428 this represents the first patenting to have been published in name of Kimiya of Sydney, Australia, whose research and development interests span a number of disciplines including medical diagnostic devices and microelectromechanical systems (MEMS and BioMEMS) with integrated microelectronics. For prior claims from the inventors Mehdi and Worsman describing a microfluidic diagnostic device, see WO2011156856.

Until 2013 Mehdi had been CTO of Geneasys, managing the development of medical diagnostic systems incorporating integrated BioMEMS and BioMEMS and CMOS lab-on-a-chip devices and utilising robotic systems for assembly and loading of the system devices and modules. By February 2016, he had also seemingly since left his position of Director at Kimiya for a position at Simavita (that has developed a Smart Incontinence Management (SIM™) medical device for residential aged care facilities).
**WO2016022754-A2**: “Method and apparatus for applying an anesthetic and bactericide.”

Assignee: Leibovici, Jacob
Inventors: Leibovici, Jacob
IPC Codes: A61M 5/31; A61M 5/42
Publication Date: 11-Feb-2016 (also published as US20150094661-A1, 02-Apr-2015);
Earliest Priority Details: US2006733757, 07-Mar-2006

Apparatus for applying an anesthetic to a patient, comprising a syringe having a liquid anesthetic, or a liquid anesthetic cartridge and a compressed gas or vapor canister therein, or a receptacle for receiving a gas or vapor canister, wherein the receptacle comprises a clip for attaching to a syringe. The invention minimizes the pain associated with conventional anesthesia techniques by applying endothermic gas or vapor to the injection site prior to the anesthetic injection and also has the benefit of the gas blanching the mucosa to enable a practitioner to readily identify the pretreated injection site such that the needle is not inserted into an unanesthetized area.

See US8500678 (granted in August 2013) in which Dr Leibovici, a practicing dentist in Florida, previously described a method and apparatus for applying an anesthetic.

Assignee: Massachusetts General Hospital
Inventors: Bighamian, Ramin; Hahn, Jin-Oh; Reisner, Andrew, T.; Yapps, Bryce
IPC Codes: G06Q 50/24; A61B 5/0402
Publication Date: 11-Feb-2016
Earliest Priority Details: US201435177, 08-Aug-2014

System for monitoring and controlling a subject’s cardiovascular state, comprising a sensor configured for acquiring cardiovascular data and a processor for analyzing the cardiovascular data. Although the invention is directed to prediction of hemodynamic responses of vasopressors, it may be extended to a variety of pharmaceutical agents and conditions. By way of non-limiting examples, pharmaceutical agents contemplated for use in the present disclosure include medications for increasing blood pressure and/or heart rate, such as epinephrine, noradrenaline, ephedrine, isoproterenol, vasopressin, and others, as well as medications for lowering blood pressure and/or heart rate, such as diltiazem, verapamil, clonidine, nitroprusside, nitroglycerine, nifedipine, nicardipine, and esmolol, as well as other pharmaceutical agents known for treating hypotensive or hypertensive conditions.

Reisnor can be seen to have quite a history of patenting in the field of medical diagnostic/monitoring device technologies, stretching back to WO2007024777 in which he described a wearable blood pressure sensor and method of calibration. Since then he has come to describe: an apparatus such as a glove or wand for blood pressure measurement by touch (WO2007064654); a clip-type ring triage sensor capable for non-invasive vital sign monitoring (US20100168531); and, a system having a communications module for interacting with a medical measurement device, an analysis controller, and a test module that allows for the testing and evaluating of decision-support algorithms (US20140149063).

In May 2015, Resinor gained some media attention for his APPRAISE (Automated Processing of the Physiological Registry for Assessment of Injury Severity) system following the publication of an article in the journal Shock demonstrating that his automated system that simultaneously analyzes blood pressure, heart rate and breathing patterns during emergency transport, could accurately detect most cases of life-threatening bleeding.

Assignee: Massachusetts Institute of Technology
Inventors: Hammond, Paula, Therese; Hyder, Md Nasim; Shah, Nisarg, Jaydeep
IPC Codes: A61L 27/18; A61L 27/58; A61L 27/56; A61L 27/54
Publication Date: 11-Feb-2016

Composite devices for promoting bone and/or tissue regeneration and methods relating to creating such composite devices, with it being demonstrated that rapid repair of large bone and/or tissue defects is achievable without complex implant surgery and/or autograft bone. The devices may consist of a porous polymer membrane that may comprise a first agent and a second agent to be released as the porous polymer membrane degrades, decomposes and/or delaminates. In one embodiment the porous polymer membrane is PLGA, the first agent is an antibiotic, namely gentamicin, and the second agent an anti-inflammatory, namely ibuprofen. Growth factors (eg bone morphogenetic protein) may also be incorporated. The devices are characterized by an ability to controllably degrade for repair of bone and/or tissue defects sustained from traumatic wounds, or congenital defects by eluting growth factors.

For prior patenting from the team, see WO2013110047 claiming osteophilic modular nanostructured multilayers that provide sustained release of bone morphogenetic proteins.
**WO2016022307-A1**: “Vented refill arrangement and associated tools for implantable drug-delivery devices.”

Assignee: Minipumps LLC  
Inventors: Brandt, William, Andrew; Dunn, Andrew; Kavazov, Julian, D.; Pham, Tuan; Schleicher, Brett, Daniel; Wessel, David, Mathew  
IPC Codes: A61M 5/158; A61M 39/02; A61M 31/00; A61M 5/142; A61M 5/162  
Publication Date: 11-Feb-2016 (also published as US20160038672-A1)  
Earliest Priority Details: US201433545, 05-Aug-2014

Implantable drug-delivery device comprising a drug reservoir, a needle containing an elongated member, a refill lumen, a venting channel and a needle tip. Various embodiments relate specifically to drug pump devices implanted into the eye (eg between the sclera and conjunctiva), however, many features relevant to such ophthalmic pumps are also applicable to other drug pump devices, such as implantable insulin pumps, inner ear pumps, and brain pumps. The inventor Dunn previously described a drug refill applicator system in WO2015100248.

MiniPumps was formed in 2008 for the commercialization of a proprietary pump technology initially developed at the California Institute of Technology and the University of Southern California. Replenish Inc was founded by the same three individuals that founded MiniPumps, and the two entities share the same address in Pasadena.

Replenish has created a small, automated, refillable ocular drug pump called the Ophthalmic MicroPump™ System. Designed to be implanted under the skin of the eye, the pump features technology to: inject programmed amounts of drug at set times; hold up to 12 months of medication before refills; be refilled using a disposable 31 gauge needle; and, recharge wirelessly. The MicroPump™ (currently in clinical investigation, and not yet approved by the US FDA for sale) is implanted under the eye’s skin for the purpose of periodically injecting sight-saving medication for patients with age related macular degeneration.
WO2016021185-A1: “Injection protocol generation device, injection device or imaging system equipped with generation device, and program for generating injection protocol.”

Assignee: Nemoto Kyorindo Co Ltd
Inventors: Dembo, Masayuki; Fukikoshi, Yumiko; Masuda, Kazumasa; Nemoto, Shigeru
IPC Codes: A61B 6/03; A61M 5/145; A61M 5/168
Publication Date: 11-Feb-2016
Earliest Priority Details: JP2014159435, 05-Aug-2014

Injection apparatus equipped with a device for generating a contrast medium injection protocol in which the pixel value in the prescribed range is retained at the imaging site i.e. from the aortic arch to the peripheral artery. It is claimed that the apparatus may be connected with an imaging device, particularly a CT apparatus but also including other imaging apparatus such as MRI, SPECT and angiography.

The figures and imagery accompanying the application suggest a possible association with Nemoto Kyorindo’s CT injector technologies that include its Dual Shot GX7 and A-800 products.

For prior patenting relating to Nemoto Kyorindo’s imaging systems and injection devices, see WO2015111401.

Assignee: RepliCel Life Sciences Inc  
Inventors: Hoffmann, Rolf; Hohlrieder, Martin  
IPC Codes: A61M 5/315  
Publication Date: 11-Feb-2016  
Earliest Priority Details: US201434140, 06-Aug-2014

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Dermal injector system comprising a handle and a guard together enclosed with a movable injector and a cartridge containing a liquid material to be injected. Useful for delivering suspensions of cells (e.g., dermal sheath cup (DSC)) for treating androgenetic alopecia and also dermal fillers, particularly hyaluronic acid, into tissues in a uniform and reproducible manner. Provides precise and targeted delivery of a liquid suspension of cells to desired tissue layers.

The system would appear to relate to Replicel's RCI-02 next-generation dermal injector that is designed to deliver cell-based products, such as RCH-01 containing DSC cells and RCS-01 (an autologous cell-based treatment utilizing non-bulbar dermal sheath cells) for treating androgenetic alopecia and the aging of skin. The dermal injector purports to be the world’s first motorized injection device with programmable depth and volume, a built-in Peltier element for pre-injection anaesthetising, and interchangeable needle head configurations. These interchangeable heads can be used to perform a variety of procedures, increase surface area coverage and speed-up procedure times. By relying on electrical power (instead of thumb pressure) and digital controls, RCI-02 aims to automate and simplify the injection process.

In January 2016, RepliCel could be seen to have been issued a European patent describing its novel injection device technologies, see EP2623146-B.
An article such as a catheter, endotracheal tube, wound dressing or prosthetic comprising a continuous path that extends across at least a portion of a surface of the article. Fluids that are transported or that travel across the surfaces of such articles can be pure fluids (without particles or suspended matter), but often such fluids contain suspended matter in the form of particles and cells. The patterned surfaces make it possible to control the flow of the fluid, the flow of the suspended particles, or both the flow of the fluid and the flow of the suspended particles. The design of surfaces can be used to reduce microbial biofilm formation, control bioadhesion and fouling due to the deposition of particulate matter (e.g., fillers, proteins and cells).

Sharklet’s sharkskin-like surface technology gained media attention in 2015 with reports of how it could keep medical devices clean and ward off bacterial superbugs. In February 2016, its website featured the following products: Foley urinary catheter; endotracheal tube; sharkskin wound dressing; central venous catheter; and, adhesively-backed film.

For prior patenting from the three collaborating parties here, see WO2016022995 describing micropatterned intraocular implants. One of the team, Dr Tony Brennan, developed the sharklet material at the University of Florida, and can be seen to have described a method of patterning a surface and articles comprising the same in WO2010056824 - which happens to cover their incorporation into class I medical devices.

Assignee: Valtronic Technologies (Holding) SA
Inventors: Lepple-Wienhues, Albrecht
IPC Codes: A61M 5/32; A61M 5/24
Publication Date: 11-Feb-2016 (also published as EP2982400-A1, 10-Feb-2016)
Earliest Priority Details: EP2014180261, 07-Aug-2014

Device for attaching to a portable liquid injection device, particularly an insulin injection pen, so as to enable the filling level of its drug reservoir to be determined. The device comprises at least two flat conductive electrodes that enable an electrical field to be applied across the drug reservoir of the injection device. The device is configured to determine the filling level of the drug reservoir from different providers with different constructions based on an algorithm employed within an electronic data processor. See EP2065064 for prior pen injector claims from Valtronic Technologies.

The inventive device may comprise intelligent features such as a microprocessor and an algorithm that can recognize and automatically learn the typical pattern of time and dosage for a given patient. Alternatively a typical pattern can be programmed into the device as well as alarm thresholds, eg by wireless data communication. In addition, the airshot pattern used by this patient (squirt a small amount of insulin into the air before injection to prime and test the hypodermic needle) will be programmable. The device will contain a microprocessor running algorithms that analyze the dosage and time and warn the patient when deviating from his typical dosage pattern using an alarm feature. The device may comprise means for acoustical, optical or vibrational warnings and alarms. In another embodiment the devices can communicate with a third device eg a smartphone or a blood glucose meter and the dosage pattern logic including alarm functions can then be also implemented in the third device. As patients frequently use two or more different injection pens containing at least a long-lasting (pen A) and a rapid acting insulin (pen B) respectively, the inventive device may comprise means featuring a key lock mechanism such that a matching device will remain on the pens and allow only the fitting of cap A to pen A and cap B to pen B, preventing confusion of the two pens with different types of insulin. Wireless communication between these devices could also ensure that the right pen is used at the correct time and dose and deviations from the correct dosage and time pattern would trigger alarms. Further, a biometric identification of the patient could be provided by a fingerprint sensor on the pen’s cap or an additional device to exclude confounding or tampering with data belonging to patient.

In February 2016, Valtronic’s website could be seen to be report its development of electronics for two different insulin pens for YPSOMED, whose advertised injector pen products at that time comprised: YpsoPen™; ServoPen™; UnoPen™; and, FixPen™.
**WO2016022928-A1**: “Adhesive compositions and patches, and associated systems, kits, and methods.”

Assignee: Xcede Technologies Inc
Inventors: Brandy, Kyle, Robert; Ericson, Daniel, Grant
IPC Codes: A61F 13/00
Publication Date: 11-Feb-2016
Earliest Priority Details: US201435250, 08-Aug-2014

Adhesive compositions and patches comprising a biodegradable solid matrix comprising fibrin and a method for making a patch comprising exposing the matrix to a dehydrating agent such that water is removed from the solid matrix. It is disclosed how the inventive articles may be employed in a wide variety of applications including eg general surgery, vascular surgery, spine surgery and ophthalmologic surgery. The articles can be configured to be applied to any type of tissue and be used to: assist hemostasis in a bleeding area, reduce blood flow from solid organs, assist in sealing suture holes, assist in sealing anastomosis or leaks from hollow organs, assist or replace sutures in surgical procedures, produce a water-tight closure across portions of tissue, reinforce tissue (eg in reinforcing suture lines including high stress suture lines), replace sutures, fill dead space or other voids in tissue, in vascular repair, as burn dressings, and/or for combined hemostasis/sealing and drug delivery. For prior patenting featured one of the team, Ericson, see WO2013116633 describing tissue patches that can be handled relatively easily and provide good structural reinforcement at a wet site, such as a bleeding wound.

Xcede Technologies, a subsidiary of Dynasil Biomedical Corp, is based in Rochester, Minnesota, and began operations in October 2013 following a technology transfer from DBM. It is focused on the development and manufacturing of innovative hemostatic and sealant products for surgical application. Xcede’s first product is a resorbable hemostatic patch to be used when conventional techniques are inadequate or impractical during general or cardiovascular surgery. Said product may relate to Xcede’s trademarking of the term OneStop™.

In January 2016, Xcede announced that it had signed three collaboration agreements with Cook Biotech Inc, including a development agreement, a license agreement and a supply agreement to complete development, seek regulatory clearance and produce Xcede’s resorbable hemostatic patch. At that time it was anticipated that clinical trials of Xcede’s resorbable hemostatic patch would start in early 2017.
WO2016022831-A1: “Syringes, kits, and methods for intracutaneous and/or subcutaneous injection of pastes.”

Assignee: Xeris Pharmaceuticals Inc
Inventors: Donovan, Martin
IPC Codes: A61M 5/31; A61M 5/178; A61M 5/28
Publication Date: 11-Feb-2016
Earliest Priority Details: US201434004, 06-Aug-2014

Pre-loaded syringe comprising a syringe body defining a reservoir, a paste disposed within the reservoir, a plunger and a luer fitting. Disclosed to be useful for intracutaneous and/or subcutaneous injection of drugs and vaccines. Seemingly represents Xeris’ first patenting to specifically describe such syringe technologies. For prior patenting from the inventor describing stable peptide formulations, and which would appear to focus on glucagon-containing formulations for parenteral injection, see WO2015120231.

In June 2014, not long before the priority date seen on the present application, Austin-based Xeris Pharmaceuticals announced that it was set to dose the first patient with a soluble glucagon for patients with type 1 diabetes in the company’s phase II clinical study, led by the Baylor College of Medicine researcher Dr Morey Haymond, as part of a new US Investigational New Drug (IND) application. The injection, Xeris’ G-Pen Mini™, is a room-temperature stable glucagon product, which the company expects to be an effective and convenient treatment for mild-to-moderate hypoglycemia or low blood sugar. Glucagon is used in diabetes but is now only approved in glucagon emergency kits, developed by Eli Lilly Company and Novo Nordisk for the treatment of severe hypoglycemia. Currently, the drug is only available in the form of dry powder, and the patients have to reconstitute it using a water-filled syringe, which is a multi-step lasting process. By creating the injection, Xeris aims to introduce a faster and more patient-friendly tool.

Perhaps significantly the present filing’s disclosure exemplifies a formulation containing an unidentified monoclonal antibody (mAb), that is perhaps not too surprising given the company’s XeriJect™ formulation system is directed to APIs consisting of large molecules such as proteins and mAbs. As hinted at above, Xeris has successfully demonstrated the development of XeriJect™ glucagon but is now said to be shifting its attention to the application of the technology to mAbs that currently require a visit to the hospital and a four-hour or longer stay for IV infusion driving up the cost of administration and overall expense of the therapies. If these drugs could be reformulated for subcutaneous injection via a simple auto-injector or patch pump, the hospital visit could be shortened or eliminated entirely thereby significantly reducing healthcare costs as a whole.
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