MEDICAL DEVICES COMMITTEE’S NEWSLETTER

May 15, 2016

Dear Readers,

Welcome to the ABA’s Medical Devices Committee’s newsletter! We strive to bring you the latest and most pertinent information on corporate, regulatory, intellectual property, product liability, and other legal issues in the field bi-weekly. Please find the newsletter below and feel free to contact me with any contributions, questions, or suggestions. I highly encourage attorneys, industry professionals, and law students to submit medical devices-related stories of interest. Have a wonderful week!

Sincerely,

Nelson Crespo

David J. Dykeman, JD                                         Nelson Crespo, JD
Committee Co-Chair                  Editor
Shareholder & Patent Attorney                Of Counsel
Greenberg Traurig, LLP                           Conan & Herman, P.A.
One International Place                     320 N. Magnolia Ave., Ste. A1
Boston, MA 02110                              Orlando, FL 32801
(617) 310-6009                                  407-872-3999
dykemand@gtlaw.com                   nelson.crespo89@gmail.com

Regulatory/Legislative/Policy

“Boston Scientific Wins FDA Nod for Rhythmia Cardiac Mapping and Ablation Catheters.” Boston Scientific has won pre-market approval from the FDA for a pair of ablation catheters that use the #D cardiac mapping technology it acquired from Rhythmia Medical in 2012. The pre-market approval covers the IntellaNav XP and IntellaNav MiFi XP mapping and ablation catheters. “With these approvals, we continue the expansion of our electrophysiology product offerings, further demonstrating our commitment to help electrophysiologists provide the highest quality of care for their patients,” said rhythm management chief medical officer Dr. Kenneth Stein, according to Mass Device. (May 4, 2016). http://tinyurl.com/jfg6hrv

“FDA Dubs Recall for B. Braun Hemodialysis System as Class I.” The recall stems from the companies Dialog+ Hemodialysis System which could allow air to enter the dialysis solution. The FDA has given this a Class I designation because the improper blood filtration could lead to serious consequences including death.
Six models totaling 1,000 units that were distributed through Oct. 7, 2015 have been recalled. A letter was issued by B. Braun on April 1 advising customers to have a technician run a pressure test according to specific instructions in the letter. If there is no drop in pressure found, customers can continue to use the machines, according to Fierce Medical Devices. (May 5, 2016). http://tinyurl.com/gvs7yb5

“Hospitals to Shift CMS Hip, Knee Implant Cost Pressure to Medical Device Makers: Report.” The Centers for Medicare and Medicaid (CMS) have implemented their Comprehensive Care for Joint Replacement program, which went into effect on April 1. This is the first mandatory bundled payment initiative from CMS for its value-based pricing scheme for hip and knee implant procedures. The program applies to 789 metropolitan hospitals with rural ones excluded. CMS expects to save about $343 million over the 5-year plan from April 2016 through December 2020, according to Fierce Medical Devices. (May 6, 2016). http://tinyurl.com/hf9mm2c

“Acutus Medical Wins CE Mark for AcQMap Image & Mapping System.” Acutus Medical won CE Mark approval in the European Union for its AcQMap high resolution imaging and mapping system designed for use with its AcQMap catheter. “The CE Mark approval of our AcQMap System marks a significant milestone for the company and for the EP community. AcQMap will provide for the first time, the ability to unlock the mysteries of cardiac activation by truly mapping complex arrhythmias in real-time...,” according to Mass Device. (May 4, 2016). http://tinyurl.com/z2lsuam

“UPDATE: Cook Medical Recalls All 4m Beacon Tip Catheters.” Cook Medical has recalled all lots of catheters using Beacon Tip locating technology. The decision for the expansion of the recall comes from increased reports that the polymer used in the tips degrades over time causing the tips to fracture. There have been about 30 reports of tip splitting to date. Part of the decision to recall more devices was that the root cause for the polymer degradation has eluded Cook’s investigators, according to Mass Device. (May 4, 2016). http://tinyurl.com/h69v6ka

Intellectual Property & Innovations

“IBM Taps Bausch + Lomb to Develop New Cataract Surgery App.” The new app being developed by IBM and Bausch + Lomb will assist surgeons in performing cataract surgeries. The app will allow doctors to access patient data from an iPhone or iPad in addition to storing patient and health related data on the IBM cloud. Surgeons will be able to access the information on digital display screens or walls in the operating room during surgery. "When you consider the mobile solutions available today, and what we're able to do as consumers, we knew we identified an area of major need to help improve efficiencies for cataract surgeons and provide excellent surgical outcomes for their patients," Andrew Chang, Bausch + Lomb's senior VP of U.S. Surgical, according to Fierce Medical Devices. (May 5, 2016). http://tinyurl.com/j6jpv7o

“AliveCor Smartphone ECG as Good as Standard Holter Monitor: Study.” AliveCor is on its way to making its smartphone-based ECG the standard-of-care for patients with undiagnosed heart palpitations. Studies have shown the Alivecor device could be used as a first-line approach to detection instead of the Holter monitor, which utilizes many inconvenient leads, by cardiologists. The AliveCor monitor is attached to the back of a smartphone and the user rests it on the chest when feeling heart palpitations. The data was presented at the Heart Rhythm Society conference in San Francisco on May 4, according to Fierce Medical Devices. (May 5, 2016). http://tinyurl.com/zbo9xfm

“Houston Startup Raises $12M to sell Orthodontic Device to Reduce Treatment Time by Half.” OrthoAccel Technologies has developed a device that will help to make the orthodontics process a lot shorter and less painful. The hands-free AcceleDent is inserted into the mouth for 20 minutes daily in addition to
orthodontics. The design helps accelerate teeth and bone movement at a cellular level by micropulses. AcceleDent was first cleared by the FDA in 2009 and is available at more than 3,000 orthodontic practices in North America and another almost 800 internationally, according to Fierce Medical Devices. (May 5, 2015). [http://tinyurl.com/zrqd5y9]

“Medtronic Offers Positive Stress Test Data on Newly Approved Leadless Pacemaker.” Medtronic’s Micra leadless pacemaker has shown consistent safety and efficacy at months after implant. The data was presented at the Heart Rhythm Society Conference in San Francisco and showed that even under maximal exertion treadmill tests, Micra offered appropriate rate-responsive pacing in a 20-patient study. The Micra Transcatheter Pacing System is less than one-tenth the size of traditional pacemakers, making it about the size of a vitamin pill, according to Fierce Medical Devices. (May 6, 2016). [http://tinyurl.com/hnuzgsv]

“UCD Team Designs New Add-on Reading Glasses Tech for the Legally Blind.” The OrCam is being produced by OrCam technologies based in Israel. Researchers at the University of California-Davis have said that the glasses, fitted with a miniature camera that uses optical character-recognition technology, could help people who are legally blind. The OrCam was released as a prototype in 2013 and is mounted on eyeglasses and can recognize text and reads it to the user through an earpiece. It can also be programmed to recognize faces and commercial products. "Age-related macular degeneration is one of the most common causes of blindness in the elderly... this device offers hope to patients who are beyond medical or surgical therapy for the condition," said Mark Mannis, co-author of the study and chair of the school's Department of Ophthalmology & Vision Science, according to Fierce Medical Devices. (May 6, 2016). [http://tinyurl.com/znqreg7]

M&A/Joint Ventures/Corporate News

“CardioFocus Readies HeartLight’s U.S. Coming-out Party at HRS 2016.” CardioFocus unveiled its HeartLight cardiac visualization and ablation device at this year’s annual Heart Rhythm Society in San Francisco. A selective U.S. launch has been planned by CardioFocus beginning in July. The device combines a compliant balloon catheter with laser energy and endoscopic visualization to allow electrophysiologists to see the tissue targeted for ablation. CardioFocus received FDA approval for the HeartLight on April 1, according to Mass Device. (May 4, 2016). [http://tinyurl.com/hkjuxdx]

“Valeritas Raises $25m Via Reverse Merger, Private Placement.” Through a reverse merger and private placement of five million shares of unregistered stock at $5 per share, Valeritas managed to raise $25 million. The Bridgewater, N.J.-based company will trade on the OTC market under the “VLRX” symbol. “This is an extremely exciting time at Valeritas as the company very recently shifted its sales strategy to more focused, high-return on investment and profitable sales growth model…, said CEO John Timberlake. Valeritas makes the V-Go basal insulin delivery system for Type II diabetes, a continuous-delivery insulin system that is fully disposable and designed to function for 24 hours, according to Mass Device. (May 4, 2016). [http://tinyurl.com/hktaxwn]

“HeartWare Dives on big Q1 Sales, Earnings Misses.” After posting Q1 earnings that badly missed Wall Street expectations, HeartWare International share prices fell. “In the 1st quarter, our international revenue performance was impacted by competitive dynamics in Germany, as well as lower implant volumes in certain other international markets…In the U.S., the bridge-to-transplant segment of the market for which the HVAD system is approved, showed softness resulting from a slowdown in the volume of patients eligible for bridge-to-transplant procedures at the start of the year …”, said president and CEO Doug Godshall in prepared remarks, according to Mass Device. (May 4, 2016). [http://tinyurl.com/z4k3v6h]
“UPDATE: Comerica’s Parkhill to Replace Longtime Medtronic CFO Ellis.” Medtronic will be hiring a new finance chief from Comerica after the retirement of CFO Gary Ellis. After a 27-year run, Ellis will step down as CFO on June 20 and will keep his seat on Medtronic’s executive committee. “Although Gary will continue in a critical leadership role at Medtronic, I cannot thank Gary enough for the leadership he provided Medtronic over the past 11 years as CFO,” chairman & CEO Omar Ishrak said in prepared remarks. Karen Parkhill’s resume includes a stint as CFO of J.P. Morgan Chase’s investment banking arm and as CFO of Comerica, according to Mass Device. (May 4, 2016). [http://tinyurl.com/z45l6ey](http://tinyurl.com/z45l6ey)

“Apple Brings on Former Google Exec to Lead iPhone Healthcare Projects.” Apple has hired former Google exec and robotics expert, Yoky Matsuoka, to lead some of its healthcare initiatives. A co-founder of Google’s X lab and former head of technology at home sensor company Nest, Matsuoka will work with Apple COO Jeff Williams and be charged with developing apps for Apple’s HealthKit, ResearchKit, and CareKit. Health care is expected to play an increasingly large role in Apple’s future in light of declining iPhone sales, according to Fierce Medical Devices. (May 5, 2016). [http://tinyurl.com/hv94ux8](http://tinyurl.com/hv94ux8)

**Lawsuits/Settlements/Investigations**

“EndoEvolution Claims Win in Patent Spat with J&J’s Ethicon.” The U.S. Patent & Trademark Office’s Patent Trial & Appeal Board denied Ethicon’s bid for an *inter partes* review of an EndoEvolution Patent. Thirty claims were challenged by the Johnson & Johnson subsidiary Ethicon. “In its written decision, however, the PTAB determined that Ethicon failed to establish that there is a reasonable likelihood of showing that any of the challenged claims are unpatentable, and that therefore the petition was denied,” EndoEvolution said, according to Mass Device. (May 2, 2016). [http://tinyurl.com/h8of7sx](http://tinyurl.com/h8of7sx)

“Johnson & Johnson Vows to Appeal $55m Talc Powder Loss.” Johnson & Johnson is facing about 1,200 lawsuits accusing the company of inadequately warning consumer about their talc-based products’ cancer risk. In the latest case, jurors in Missouri returned a verdict for Gloria Ristesund awarding her $5 million in compensatory damages and $50 million in punitive damages. J&J has planned to appeal the verdict. “Unfortunately, the jury’s decision goes against 30 years of studies by medical experts around the world that continue to support the safety of cosmetic talc. We understand that women and families affected by ovarian cancer are searching for answers, and we deeply sympathize with all who have been affected by this devastating disease with no known cause. Johnson & Johnson has always taken questions about the safety of our products extremely seriously…spokeswomen Carol Goodrich said in prepared remarks, according to Mass Device. (May 4, 2016).

“Correction: Federal Appeals Court Denies Endotach in Medtronic Stent Graft Patent Case.” A U.S. Patent & Trademark Office decision was upheld by a federal appeals court. The decision from the USPTO invalidated a stent patent licensed to Endotach, a subsidiary of patent troll Acacia Research, in its patent battle with Medtronic. Endotach sued Medtronic in 2012 alleging that they infringed a pair of patents licensed by Endotach. The lawsuit was filed in the U.S. District Court for Northern Florida and accused Medtronic of violating the patents with its Trident, Valiant, and Endurant stent grafts. The U.S. Court of Appeals for the Federal Circuit issued the denial without comment, according to Mass Device. (May 6, 2016). [http://tinyurl.com/gt9ey4q](http://tinyurl.com/gt9ey4q)

“Unilife Plunges After Canceling Earnings Call on ex-CEO’s Possible ‘violations.’” After its discovery of possible company policy and legal “violations” by former chairman & CEO Alan Shortall Unilife canceled an earnings conference call causing shares to plummet. “The company is investigating these matters and their potential impact on financial reporting and internal controls over financial reporting, related to previously-issued financial statements, current interim financial information, and management’s certifications. The
investigation has just commenced due to the recent discovery by current management but has not to date
discovered any financial loss to the company,” Unilife said, according to Mass Device. (May 9, 2016).
http://tinyurl.com/jj4k4wy

“Appeals Court Denies Biolitec in Angiodynamics Spat.” Germany-based Biolitec’s challenge to a federal
court ruling which was issued in favor of Angiodynamics has been denied and possible contempt sanctions were
issued against the German medical laser maker. Biolitec reportedly violated a preliminary injunction and
appealed the resulting civil contempt order entered by the district court. The company argued in its challenge
that the district court which ruled against them lacked the authority to set a cap for the sanctions against it,
saying the “underlying preliminary injunction expired by its own terms and so the district court can no longer
coerce compliance with it.” The 1st Circuit Court denied the appeal stating it did so because Biolitec “failed to
raise this argument at any time prior to the present appeal,” according to Mass Device. (May 9, 2016).
http://tinyurl.com/zceu5yj

Click here to join the Section of Science & Technology Law’s Medical Devices Committee to receive this
newsletter weekly.