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JUNE 2014 MONTH-END INDUSTRY NEWS 0 **MOB DIGITAL MAGAZINE**

Monday, 30 June 2014

Here is the latest batch of news from the medical products community. Please click the link for more.

Regulatory Approvals and Launches

Argo Medical Technologies, Inc., Marlborough, MA, and Yokneam Ilit, Israel, reports that the FDA has allowed marketing of its ReWalk, the first motorized device intended to act as an exoskeleton for people with lower body paralysis due to a spinal cord injury.

Ulrich Medical USA Inc., Chesterfield, MO, has launched its uCentum comprehensive posterior system in the US for open and minimally invasive spinal fusion applications.

Edwards Lifesciences Corporation, Irvine, CA, reports that the FDA has approved its Sapien XT transcatheter aortic heart valve to treat high-risk and inoperable patients with severe aortic stenosis.

InspireMD, Inc., Boston, MA, a leader in embolic protection systems (EPS), has received European regulatory approval to resume the manufacturing of its MGuard Prime EPS stent with a modified stent securement process. The company also received approval to modify and re-deploy existing MGuard Prime EPS stents that have been returned by clinical and commercial sites worldwide.

ERT, Philadelphia, PA, a leading global solution provider for patient safety and efficacy endpoint data collection, has received FDA 510(k) clearance to market its AM3[®] GSM devices, which provide a wireless option for clinical trial patients to communicate key spirometry data, in respiratory clinical trials.

Devon Medical Products, Inc., King of Prussia PA, an ISO 13485 medical device manufacturer, designer, and distributor, announced that it has received FDA 510(k) clearance to market its extriCARE[®] 3600 Negative Pressure Wound Therapy pump and foam dressing kit.

FUJIFILM Medical Systems U.S.A., Inc., Stamford, CT, a global leader in technology innovation, has received FDA 510(k) clearance for its Aspire Cristalle imaging system for digital mammography.

Sparta Systems, Inc., Hamilton, NJ, a global leader in enterprise quality management solutions (EQMS), has received ISO 9001:2008 certification for the design and distribution of its software. The company is the first and only major EQMS vendor to have received this certification.

Leadership News

Mack Molding, Arlington, VT, announced that **Ray Burns**, president of Mack's Southern Division, announced plans to retire as of September 1. He has been with Mack for 33 years, and as president of the division for the past 17 years. **Bryan Campbell**, Mack North headquarters plant manager, has been named as the new president of the Southern Division. Replacing Campbell, **Rich Hornby** was promoted to plant manager of the Mack Molding headquarters plant in North Arlington, VT.

Medtronic, Inc., Minneapolis, MN, announced that it is promoting **Geoff Martha**, currently Senior Vice President for Strategy and Business Development, to Chief Integration Officer as it proceeds with its acquisition and integration of **Covidien plc**, Dublin, Ireland.

NeoChord, Inc., Eden Prairie, MN, a medical device company focused on minimally invasive mitral valve repair, has appointed **David Chung** as President and Chief Executive Officer, effective immediately, replacing **John Seaberg**, who resigned. The company also announced that **Michael Fulton**, a company director, has been elected as Chairman of the Board.

Sunshine Heart, Inc., Eden Prairie, MN, an early-stage medical device company focused on developing, manufacturing, and commercializing its C-Pulse Heart Assist System to treat heart failure, announced the appointment of **Brian Brown** to the position of Senior Vice President of Operations and Technology.

Sunstone Circuits, Mulino, OR, a leading printed circuit board prototype solutions provider, has named **Dennis Hammer** as Quality Assurance Manager, where he will manager product quality, continuous improvement, and process analysis.

HLT, Inc., Maple Grove, MN, a medical device company developing leading-edge transcatheter aortic valve replacement therapy, announced the addition of **Kevin Bassett** as General Manager.

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