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SYSTEM ELIMINATES NEED FOR CATHETER

Medtronic stays on course with FDA nod for Cardioinsight mapping system

By Omar Ford, Staff Writer

Medtronic plc has won FDA clearance for its Cardioinsight noninvasive 3-D mapping system. The device, which has been approved in Europe for nearly five years, is used to improve the mapping of electrical disorders of the heart. The Dublin-based company first gained access to the device through its $93 million acquisition of Cleveland-based Cardioinsight Inc. (See *Medical Device Daily*, June 22, 2015.)

The device could become a safer and less costly alternative to traditional cardiac mapping procedures, which are typically accomplished by inserting a catheter into the heart via an artery or vein. The Cardioinsight system eliminates

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OPTIONS FOR DRUG-RESISTANT PATIENTS

Vascular Dynamics gains FDA Expedited Access Pathway designation for hypertension implant

By Stacy Lawrence, Staff Writer

Vascular Dynamics Inc. has been added to the FDA's Expedited Access Pathway (EAP)program for its Mobiushd device to treat resistant hypertension. The implant is designed to amplify the signals received by baroreceptors located in the carotid

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REGULATORY

Biotronik says no devices detained despite threat in FDA warning letter

By Mark McCarty, Regulatory Editor

Some FDA inspections go better than others, and the March 2016 inspection of the plant operated in Berlin by Biotronik SE & Co. KG of Berlin did not go well, as indicated by the Sept. 1, 2016, warning letter. While the agency said it would detain devices made at the company's Berlin plant, Biotronik

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EXPANDING TO ALL HEART CHAMBERS

Ventripoint's complete VMS blood volume measuring system awaits Canadian approval

By David Godkin, Staff Writer

Toronto's Ventripoint Diagnostics Ltd. is seeking Health Canada approval for expansion of a knowledge-based reconstruction system to measure blood volumes in all four chambers of the human heart. This follows successful testing of the VMS's analysis of the right and left atriums and left ventricles of the heart, and a year and a half after the FDA approved its use for assessing blood volumes in the right ventricle, the most difficult heart chamber to analyze.

"Once we showed that we could provide a reconstruction model for the right ventricle, we were pretty sure we could do it with the other three chambers," company president and CEO George Adams told *Medical Device Daily*. "People

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OTHER NEWS TO NOTE

Genomedx Biosciences, of Vancouver, British Columbia, said it entered into a research collaboration with **Astellas Pharma Inc.**, of Tokyo, to apply genomic tumor profiling using Genomedx's Decipher Classifier and Decipher Grid as a potential aid in the identification of prostate cancer patients undergoing active surveillance who may benefit from treatment with Xtandi (enzalutamide). As part of the agreement, Astellas will provide Genomedx with tumor samples from its phase II ENACT trial, which is comparing the time to prostate cancer progression between patients treated with enzalutamide versus patients undergoing active surveillance. Genomedx will profile all samples to provide Astellas with an analysis of tumor aggressiveness.

Invacare Corp., of Elyria, Ohio, reported a reduction in its workforce of about 100 associates. This reduction is part of the company's larger effort to be more efficient, and it is expected to generate approximately $6.6 million in annualized pretax savings. Invacare is in the midst of a three-phase business transformation from a generalist durable medical equipment company to one that focuses its strong technical capabilities on solving complex clinical needs for post-acute care.

Opko Health Inc., of Miami, reported its subsidiary and business unit, Genedx, is entering into a collaboration with the Deciphering Developmental Disorder (DDD) study led by the **Wellcome Trust Sanger Institute** in Cambridge, U.K. The DDD study aims to determine the clinical utility of leveraging advanced genomic technologies to diagnose patients with developmental disorders. This goal will be accomplished by identifying genes and pathways for human genetic diseases and characterizing the associated phenotypes, and improving informatics and statistical methods to diagnose patients with genetic conditions.

Personal Genome Diagnostics Inc., of Baltimore, said it has been awarded an SBIR contract from the National Cancer Institute for the development of a diagnostic to help identify patients who are most likely to benefit from treatment with immuno-oncology cancer drugs known as checkpoint inhibitors. PGDx will use the phase I contract to develop Mutatordetect, a cost-effective liquid biopsy assay that can quantitatively assess patient tumor mutational load. PGDx expects to complete initial development of the assay this year.