FDA Rule Mandating Unique Device Identification for Reusable Medical Devices Creates New Market Opportunity for VeriTeQ in Breast Implant Sizers and Other Reprocessed Devices

Business Wire

Digital Angel Corporation, a provider of implantable medical device identification and radiation dose measurement technologies, following its recent share exchange with VeriTeQ Acquisition Corporation (“VeriTeQ”), discussed today a new market opportunity for identifying breast implant sizers, which was created, in part, by the U.S. Food and Drug Administration (“FDA”) Final Rule for Unique Device Identification (“UDI”), announced on September 20, 2013. The Company estimates the breast implant sizer market at approximately 600,000 devices annually.

Breast implant sizers are used temporarily during breast augmentation surgery prior to the placement of the permanent breast implant to assist in determining the desired breast implant volume, and then re-sterilized for their next use. The Final Rule for UDI requires all medical devices distributed in the U.S. that are intended to be used more than once and intended to undergo any form of reprocessing before each use to carry a UDI with “direct part marking” of the device. VeriTeQ’s Q Inside Safety Technology, a FDA cleared radio frequency identification (“RFID”) microchip, can act as a direct part marking that can be included within a reusable, reprocessed, or implantable medical device and read with a handheld scanner.

Sizers, used by the world’s leading manufacturers of breast implants, are similar to typical breast implants made of gel silicone and are intended for a maximum of ten additional reuses following sterilization after each use. The Company believes the Final Rule also may provide potential market opportunities to identify other reusable or reprocessed medical devices such as artificial joint sizers, heart valve sizers, surgical equipment, and endoscopy devices, among others.

“Over the past several months, in conjunction with a global breast implant manufacturer we are working with, we have successfully manufactured Q Inside Safety Technology into their breast implants, with the goal of providing manufacturers and patients a quality control and safety device to enhance their implants. With the recent FDA mandate to directly mark reusable devices with a UDI, we believe the use of Q Inside Safety Technology for breast implant sizers becomes more relevant,” stated Scott R. Silverman, Chairman and Chief Executive Officer of VeriTeQ. “Like the opportunity in the breast implant sizer market, we also believe that there are undiscovered opportunities in other categories of the reusable medical device market that we intend to pursue diligently.” The FDA Rule was issued in response to the passage of the FDA Safety and Innovation Act, which directed the federal agency to develop regulations that would create a UDI system for medical devices.

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