VeriTeQ’s Patented and FDA Cleared Technology Can Help Medical Device Manufacturers Comply with FDA Proposed Rule for Unique Device Identification – Direct Mark Requirement

Business Wire

Digital Angel Corporation (“Digital Angel” or the “Company”) (OTC Markets: DIGA), a provider of implantable medical device identification and radiation dose measurement technologies following its recent share exchange with VeriTeQ Acquisition Corporation (“VeriTeQ”), announced today that the patented VeriTeQ “Q Inside” radio frequency identification (“RFID”) microchip, cleared by the U.S. Food and Drug Administration (“FDA”), can help implantable medical device manufacturers comply with the FDA’s Proposed Rule for Unique Device Identification (“UDI”) – Direct Mark requirement.

The FDA’s Proposed Rule for UDI reflects in § 801.50 a direct marking requirement recommended for implantable medical devices because these devices present unique risks that would be better controlled through such a direct marking (versus simple labeling on the outside of the medical device packaging). The Company believes that its VeriTeQ microchip, “Q Inside,” is the only proven direct mark technology of its kind that provides Automatic Identification and Data Capture (AIDC) technology as required for implantable medical devices under the FDA’s Proposed Rule. The UDI Regulation has been released from the FDA to the White House Office of Management and Budget, and the final review is currently underway. It is anticipated that the UDI Regulation is scheduled to be released very soon.

“We believe we are uniquely positioned with our FDA cleared technology and have an early mover advantage to give major medical device manufacturers the ability to comply with the direct mark requirement of FDA’s Proposed Rule,” stated Scott R. Silverman, Chairman and CEO of Digital Angel. “More importantly, however, our “Q Inside” technology not only can help device manufacturers, but ultimately can enable a patient’s healthcare team to have accurate and timely access to data about an implantable medical device, in vivo, on demand, in the event of a recall or other safety event. We are not aware of any other currently available and proven technology that has this ability.” VeriTeQ has a broad intellectual property portfolio that includes more than 100 patents issued, patents pending, and patent licenses. VeriTeQ’s core technologies are FDA Cleared and CE marked, which is a key indicator of a product’s compliance with legislation in the European Union.

On July 9, 2012, the FDA Safety and Innovation Act was signed into law. In conjunction with that legislation, the FDA proposed a new rule for a UDI System, which would, among other things, allow more accurate reporting of adverse event reports so that problem devices can be identified and corrected more quickly;

reduce medical errors by enabling health care professionals to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device; provide a consistent way to enter information about devices in electronic health records and clinical information systems; provide a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls; and provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.

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