Temperature-Resistant Microchip to be Used for UDI Compliance for Implantables

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"), announced that VeriTeQ filed a provisional patent with the U.S. Patent and Trademark Office in September 2012 for a microchip that is able to withstand high temperatures in order to make it compatible with the sterilization processes involved in the manufacturing of implantable medical devices. The first application for this temperature-resistant microchip that the Company is focused on is the identification of breast implants.

The Company is working with implantable medical device manufacturers to incorporate its FDA cleared passive radio frequency identification ("RFID") microchip, referred to as "Q Inside," within breast implants and other medical devices to enable the devices to be quickly and safely identified from outside the body. The Company believes "Q Inside" is the only proven direct marking 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 for Unique Device Identification ("UDI").

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 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 final UDI Regulation will be released in the near future.

"We are focused on continually improving our technology in order to provide implantable medical device manufacturers a solution that will help them comply with the FDA's Proposed Rule for UDI," stated Scott R. Silverman, Chairman and Chief Executive Officer of Digital Angel. "We believe our portfolio of microchip and related technology applications, which currently includes more than 100 patents issued, patents pending, and patent licenses, makes us a technology leader within the industry."

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