

Integrity Applications Receives CE Mark for Its GlucoTrack® Model DF-F Glucose Monitoring Device



Integrity Applications, Inc. (OTC/QB: IGAP) announced on June 4, 2013 that it has received CE Mark approval for its GlucoTrack® DF-F non-invasive blood glucose measurement device. Receipt of the CE Mark allows Integrity Applications to market and sell the GlucoTrack DF-F glucose monitoring device in European Union (EU) member countries that have adopted the MDD without being subject to additional national regulations with regard to demonstration of performance and safety (although certain EU member countries may request or require additional performance and/or safety data from time to time, on a case-by-case basis). The CE mark also permits the sale in countries that have an MDD Mutual Recognition Agreement with the EU.

"This is a major milestone for Integrity," said Avner Gal, president and chief executive officer of Integrity Applications. "Receipt of the CE Mark positions Integrity Applications to accelerate its discussions with distributors in the EU and other countries and, eventually, to offer to diabetics in the EU a solution that allows them to test themselves more frequently without the pain of needle pricks, and the inconvenience and cost of test strips in the day-to-day management of their disease. We know that taking frequent blood glucose measurements improves patient care by facilitating glycemic control, and we believe that non-invasive testing will encourage more frequent measurements by diabetics."

The GlucoTrack DF-F was approved based on clinical data collected utilizing more than 6,000 measurements during 2012 at the Soroka University Medical Center in Israel, which showed a positive correlation between GlucoTrack DF-F readings and those obtained from an invasive device.

Source: Integrity Applications
Published on: Thu, 6 Jun 2013