June 7, 2013

Biosense Technologies Private Limited ("Biosense") recently received an undated "It Has Come to Our Attention Letter" regarding its uChek Urine analyzer mobile application ("uChek") from the U.S. Food and Drug Administration ("FDA"), Office of In Vitro Diagnostics and Radiological Health. This type of letter has been used infrequently by the FDA in public matters in the recent past. Several such letters were sent in 2010, by way of example, to genetic testing companies regarding genetic tests for use in the home. In the past, these letters have been followed by further FDA action such as Warning Letters.

The FDA requests that Biosense, within thirty (30) business days of receipt of the letter, provide either uChek's FDA clearance number or its basis for determining that uChek is not required to obtain FDA clearance. It is significant that the FDA has provided Biosense these two alternatives, one of which allows Biosense to advocate its regulatory position.

uChek is a semi-automated urinalysis system that enables iPhone cameras to analyze the presence of analytes such as glucose, pH, blood, and protein in urine. Users may download uChek from the iTunes App Store to interpret urine dipsticks for the purpose of diagnosing, for example, urinary tract infections or complications of diabetes. According to the FDA, because Biosense intends to promote uChek for use in "analyzing, reading, and/or interpreting" dipsticks, the urinalysis test system—meaning the strip reader and the test strips used together—constitutes a medical device that requires 510(k) clearance.[1] In its letter, the FDA suggests that Biosense review the decision summary by the FDA for a similar type of urine analyzer using test strips. Note that the test strips used with uChek have received 510(k) clearance for direct visual readings.

The extent to which mobile applications are within the FDA's jurisdiction has not yet been established conclusively. On July 21, 2011, the FDA released draft guidance that announced its intent "to apply its regulatory requirements solely to a subset of mobile apps" termed "mobile medical apps." Mobile medical apps are mobile applications that meet the definition of a device pursuant to the Food, Drug, and Cosmetic Act[2] and either are used as an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.

In her testimony before Congress on March 21, 2013, Christy Foreman, the Director of the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH) at the FDA, confirmed the FDA's intentions to regulate mobile medical applications according to the roadmap set forth in its draft guidance. Ms. Foreman advocated the importance of "a balanced approach to mobile medical applications that supports continued innovation, assuring appropriate patient protections." In a blog post on its website, the FDA indicated that it will issue a final guidance document regarding the governance of mobile medical applications "in coming weeks…that will help companies determine whether their product will require FDA clearance or approval."

As innovation continues in the area of mobile health, it is imperative that all parties in the space continue to monitor all applicable regulations and guidance, Government working group activity, FDA pronouncements, and Congressional initiatives relating to mobile medical applications and clinical support software.

Notes

1. Sec. 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register to notify the FDA of their intent to market a medical device at least 90 days in advance.
2. Sec. 201(h) of the Food, Drug and Cosmetic Act defines a medical device as: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a

component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body or man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."