Letter to Biosense Technologies Private Limited concerning the uChek Urine Analyzer

U.S. Food & Drug Administration

It Has Come to Our Attention Letter

Myshkin Ingawale
C/O Sumit Singh
Biosense Technologies Private Limited
212 Hockney Avenue
MOUNTAIN VIEW, CA 94041
Document Number: GEN1300289

Dear Myshkin Ingawale:

It has come to our attention that you are currently marketing the uChek Urine analyzer, which is intended for use with Siemens Multistix SG10, Siemens Multistix SG, Siemens Uristix, Bayer Diastix, and Bayer Keto-Diastix reagent strips for the qualitative and semi-quantitative determination of urine analytes including glucose, urobilinogen, pH, ketone, blood, protein, bilirubin, nitrite, leukocyte, and specific gravity. The uChek Urine analyzer appears to meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act. Please note that though the types of urinalysis dipsticks you reference for use with your application are cleared, they are only cleared when interpreted by direct visual reading. Since your app allows a mobile phone to analyze the dipsticks, the phone and device as a whole functions as an automated strip reader. When these dipsticks are read by an automated strip reader, the dipsticks require new clearance as part of the test system. Therefore, any company intending to promote their device for use in analyzing, reading, and/or interpreting these dipsticks need to obtain clearance for the entire urinalysis test system (i.e., the strip reader and the test strips, as used together). For an example of this type of device system, and a summary of the type of data used to support clearance of the system, see the decision summary for k111221 (http://www.accessdata.fda.gov/cdrh_docs/reviews/K111221.pdf [1]).

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance number for the uChek Urine analyzer. We request that you provide us with the FDA clearance number for the uChek Urine analyzer. If you do not believe that you are required to obtain FDA clearance for the uChek Urine analyzer, please provide us with the basis for that determination. Please provide the requested information within thirty (30) business days.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

James L. Woods, WO66-5688
Deputy Director
Patient Safety and Product Quality
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, please feel free to call Amy Ghering at 301-796-1656 or at Amy.Ghering@fda.hhs.gov [2], or log onto our web site at www.fda.gov [3] for general information relating to FDA device requirements.

Sincerely yours,

James L. Woods
Deputy Director,
Patient Safety And Product Quality
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/reviews/K111221.pdf
[2] http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/mailto:Amy.Ghering@fda.hhs.gov
[3] http://www.fda.gov