DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 27, 2014

BE Technologies, Inc.
% Angela Mallery
Sr. Medical Research Manager, Regulatory
NAMSA
4050 Olson Memorial Highway, Suite 450
Minneapolis, MN 55442

Re: K142425
Trade/Device Name: Uroflowmeter
Regulation Number: 21 CFR 876.1800
Regulation Name: Urine Flow or Volume Measuring System
Regulatory Class: Class II Exempt
Product Code: EXY
Dated: August 29, 2014
Received: August 29, 2014

Dear Angela Mallery,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -A

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142425

Device Name
Urine Flow Monitor

Indications for Use *(Describe)*
The UFM is a urine flow measuring system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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6.0 510(k) Summary

Submitter:	BE Technologies, Inc. 2939 20th Avenue San Francisco, CA, 94132 (415) 307-8531 Edward Belotserkovsky edbelo@sbcglobal.net
Contact Person:	Angela Mallery Sr. Medical Research Manager, Regulatory NAMSA
Date Prepared:	August 25, 2014
Device Name:	Urine Flow Monitor
Device Common Name	Uroflow meter
Device Class and Classification Regulation:	Uroflow meter 21 CFR 876.180 Product Code EXY
Predicate Device:	Company Name: Laborie Brand Name: Uroflowmetry Analyzer; UroCap. 510(k) Number: UroCap is 510(k) exempt.
Device Description:	The UFS provides real-time urine flow measurement, in men, by analyzing specific sound areas that are produced by the urine as it impacts the water surface. The system consists of a laptop with proprietary software and a microphone to capture the sound. Real time urine flow is displayed on the monitor during the test and Maximum Flow; Average Flow; Volume; Time to Maximum and Void Time are calculated and displayed on the monitor upon completion of the test.
Indication for use	The UFM is a urine flow measuring system.
Device Characteristics Compared to the Predicate	The predicate device calculates flow based on weight; the UFM is based on sound, both methods are scientifically sound. Performance testing has demonstrated the UFM and the predicate device have equivalent technological characteristic for measuring urine flow. Both devices have the ability to capture flow rates at the maximum limits of male urination.

Performance Data:	The UFM and predicate device have an equivalent accuracy related to flow and volume.
Software Verification and Validation Testing	Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "MINOR" level of concern.
Conclusion:	BE Technologies believes the UFM is substantially equivalent to the predicate device. The conclusions drawn from the performance testing demonstrate that the device is equivalent and is as safe and effective as the predicate device.