K121165

JUN 21 2012

510(k) SUMMARY

Section 5.0

Applicant:	Beam Technologies, LLC P.O. Box 17541 Louisville, KY 40217
Applicant Correspondent:	Alex Curry Head of Product Beam Technologies, LLC P.O. Box 17541 Louisville, KY 40217 Telephone: 859.462.7562 Email: curry@beamtoothbrush.com
Date Summary Prepared:	April 13, 2012
Proprietary Name of Device:	Beam Brush/ Beam App
Generic/Classification Name:	Toothbrush, Manual
Product code (Classification):	EFW (Class I, 21 CFR 872.6855)
Legally Marketed Predicate Device:	Oral-B® "sub-brand" manual toothbrush (K073224) (i.e. CrossAction, Advantage, Pulsar, Pro-Health) Procter & Gamble

DEVICE DESCRIPTION AND TECHNOLOGICAL CHARACTERISTICS

The Beam Brush is a manual toothbrush comprised essentially of a shaft with synthetic bristles on one end that are used to remove plaque and food debris from its user's teeth. The bristle material is Nylon 612 or Polyamide 612. The Beam Brush collects brushing usage data based on the principle that the human body possesses the property of being a good capacitor, such that the human body has a detectable capacitance. This capacitance is transferrable through a thermoplastic material. The Beam Brush comprises a capacitive sensor, which is completely enclosed in the toothbrush body. The capacitive sensor detects that the Beam Brush is in use based on the capacitance introduced by the human body when the Beam Brush is utilized for its intended purpose.

The Beam Brush wirelessly transmits the collected data using radio frequency transmission, more specifically Bluetooth® radio. The Bluetooth® standard defines the parameters for transmission of data via radio frequency including a transmitting frequency of 2.4 GHz. The Beam Brush is a Class 2

Bluetooth® device, which has a transmission range of about 30 feet and a maximum power of 2.5 mW. The data is received by a user's own mobile device that runs a software application (Beam App), which is of a minor level of concern. The Beam App is an accessory to the Beam Brush and allows the user to view his/her brushing usage data for the user's convenience and education. The Beam App, collection of data, and transmission of data are not intended for the diagnosis and treatment of disease or to affect the structure or function of the body.

The Beam Brush's capacitive sensor and Bluetooth® radio are powered by a single AA alkaline battery that is replaceable. The Beam Brush also comprises a replaceable brush head that connects to the handle at the base of the neck.

INDICATIONS FOR USE

The Beam Brush is a toothbrush to remove plaque and debris from its user's teeth and aide in the prevention of tooth decay. The Beam Brush collects brushing usage data and wirelessly transmits the data to a software application (Beam App) that runs on the user's own mobile device ("smartphone").

TESTING

The Beam Brush was tested to determine the pull-off force of the brush head when it is improperly removed from the handle. This test demonstrates the substantial equivalence to legally marketed toothbrushes of the replaceable head of the manual toothbrush to remain connected during the normal course of brushing.

The Beam Brush is an alkaline battery operated manual toothbrush. All electrical components including the capacitive sensor and the Bluetooth® radio are housed within thermoplastic enclosures.

The Beam Brush will be evaluated and will comply with the applicable requirements of international standard IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Second Edition, 1988). The Beam Brush also will be evaluated and comply with the applicable requirements of international standard IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests (Second Edition, 2001). Additionally, the Beam Brush will be evaluated and will comply with the applicable requirements of Equipment Authorization by the Federal Communications Commission. Collectively, these evaluations and compliances demonstrate the Beam Brush's substantial equivalence to legally marketed toothbrushes in regard to electrical safety and electromagnetic compatibility.

The Beam Brush/Beam App completed software verification and validation testing. Collectively, these tests demonstrate that the Beam Brush/Beam App is substantially equivalent to legally marketed toothbrushes when using a software application that runs on the user's own mobile device.

CONCLUSIONS

The information provided supports the substantial equivalence to the predicate device of the Beam Brush/Beam App without raising any new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Alex Curry
Head of Product
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Louisville, Kentucky 40217

JUN 21 2012

Re: K121165
Trade/Device Name: Beam Brush/Beam APP
Regulation Number: 21 CFR 872.6855
Regulation Name: Manual Toothbrush
Regulatory Class: I
Product Code: EFW
Dated: April 13, 2012
Received: April 17, 2012

Dear Mr. Curry:

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); 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), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Section 4.0

510(k) Number (if known): K121165

Proprietary Device Name: Beam Brush/ Beam App

Indications for Use: The Beam Brush is a toothbrush to remove plaque and debris from its user's teeth and aide in the prevention of tooth decay. The Beam Brush collects brushing usage data and wirelessly transmits the data to a software application (Beam App) that runs on the user's own mobile device ("smartphone").

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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