DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 18, 2017

Scientific Intake
% Janice M. Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K171165
Trade/Device Name: SmartByte Device
Regulation Number: 21 CFR§ 876.5981
Regulation Name: Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss
Regulatory Class: II
Product Code: ONY
Dated: April 20, 2017
Received: April 20, 2017

Dear Janice M. Hogan:

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 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,

Benjamin R. Fisher -S

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 on last page

510(k) Number *(if known)*

K171165

Device Name

SmartByte Device

Indications for Use *(Describe)*

The SmartByte device is intended to aid in weight management in overweight to obese individuals. The device is indicated for individuals with a body mass index (BMI) in the range of 27-35 kg/m^2 in conjunction with behavioral modification instruction.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Scientific Intake's SmartByte Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Scientific Intake
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Suite 503
Lawrence, MA 01843
E-mail: mgibeley@scientificintake.com
Phone: 978 626 2637
Contact Person: Marc Gibeley, CEO

Date Prepared: May 11, 2017

Name of Device: SmartByte Device

Common or Usual Name: Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss (Product Code: ONY)

Predicate Device: Sensor Monitored Alimentary Restriction Therapy (SMART) Device (DEN150033; Product Code ONY)

Intended Use / Indications for Use

The SmartByte device is intended to aid in weight management in overweight to obese individuals. The device is indicated for individuals with a body mass index (BMI) in the range of 27-35 kg/m^2 in conjunction with behavioral modification instruction.

Device Description

The Scientific Intake SmartByte device is an oral removable palatal space occupying device that includes a temperature recording sensor to monitor usage. The device includes a Palatal Mold Kit used by a healthcare professional to make the SmartByte device and an optional SmartByte Reader component that connects to a mobile application wirelessly via Bluetooth to allow usage data to be uploaded to assess frequency of device usage, *i.e.*, adherence and patient reported weight management.

Comparison of Technological Characteristics

The purpose of this 510(k) is to modify the predicate SMART device by converting the existing computer-based software to a wireless mobile application. No changes have been made to the SmartByte Device oral component that is inserted and removed by the patient to achieve the intended use. A detailed comparison between the predicate SMART device and the subject SmartByte device is provided below:

	Subject SmartByte Device	Predicate SMART Device (DEN150033)	Substantially Equivalent (Yes or No)
Intended Use	Aid weight management in overweight to obese individuals The SmartByte device is intended for prescription use only	Aid weight management in overweight to obese individuals The SMART device is intended for prescription use only	Yes; Same
Indications for Use	For individuals with a body mass index (BMI) in the range of 27-35 kg/m^2 in conjunction with behavioral modification instruction	For individuals with a body mass index (BMI) in the range of 27-35 kg/m^2 in conjunction with behavioral modification instruction	Yes; Same
User Population	Individuals with a body mass index (BMI) in the range of 27-35 kg/m^2	Individuals with a body mass index (BMI) in the range of 27-35 kg/m^2	Yes; Same
Technological Characteristics	Removable palatal space occupying device that includes a temperature recording sensor to monitor usage	Removable palatal space occupying device that includes a temperature recording sensor to monitor usage	Yes; Same
Palatal Mold Kit	Used by a healthcare professional to make the SmartByte device	Used by a healthcare professional to make the SMART device	Yes; Same
Optional Component	A SmartByte Reader that allows usage data to be uploaded to assess frequency of device usage, i.e., adherence and patient reported weight management wirelessly	A SMART Reader that allows usage data to be uploaded to assess frequency of device usage, i.e., adherence and patient reported weight management	Yes; Substantially Equivalent
Use	To be worn during all eating episodes	To be worn during all eating episodes	Yes; Same
Biocompatibility	The SmartByte device has been shown to be biocompatible per ISO 10993	The SMART device has been shown to be biocompatible per ISO 10993	Yes; Same
Sterilization	Not sold sterile or sterilized by user	Not sold sterile or sterilized by user	Yes; Same
Shelf Life	Same labeled shelf life	Same labeled shelf life	Yes; Same
Optional User Interface	SmartByte App interface with basic progress information provided to user	PC website portal interface with basic progress information provided to user	Yes; Substantially Equivalent

Verification and Validation Activities

Software verification and validation was performed and results demonstrated that the SmartByte and SmartByte added mobile software application (SmartByte App) are appropriate for release. In addition, the company completed testing per IEC 60950-1 for the added Bluetooth connection.

Conclusions

The subject SmartByte device is substantially equivalent to the predicate SMART device, with the same intended use and indications and minor technological differences. The conversion of the software platform to a mobile medical application with a wireless Reader does not raise new types of safety or effectiveness questions. The confirmatory software verification and validation testing, as well as testing to IEC 60950-1, further demonstrates that the device performs as intended and is substantially equivalent to the predicate device.