DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 26, 2016

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

Re: DEN150033
Sensor Monitored Alimentary Restriction Therapy (SMART) Device
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR§ 876.5981
Regulation Name: Oral removable palatal space occupying device for weight management and/or weight loss
Regulatory Classification: II
Product Code: ONY
Dated: July 31, 2015
Received: July 31, 2015

Dear Ms. Hogan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Sensor Monitored Alimentary Restriction Therapy (SMART) Device, a prescription device under 21 CFR Part 801.109 that is indicated as follows:

> *The SMART 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.*

FDA concludes that this device should be classified into class II. This order, therefore, classifies the SMART Device, and substantially equivalent devices of this generic type, into class II under the generic name, oral removable palatal space occupying device for weight management.

FDA identifies this generic type of device as:

> **Oral removable palatal space occupying device for weight management and/or weight loss**. An oral removable palatal space occupying device for weight management and/or weight loss is a prescription device that is worn during meals to limit bite size, thereby reducing the amount of food that is consumed. The device may contain recording sensors for monitoring patient use. This classification does not include devices that are intended to treat any dental diseases or conditions.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On July 31, 2015, FDA received your *de novo* requesting classification of the SMART Device into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SMART Device into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the SMART Device indicated as follows:

> *The SMART 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.*

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Tooth Movement, Irritation and Soreness of Mouth or Gums • Improper mold making • User error • Damage to material (soft edge separation)	Non-clinical Performance Testing Labeling Training
Choking or Gag Reflex	Clinical Performance Testing Labeling
Adverse Tissue Reaction	Biocompatibility Evaluation

Identified Risk	Mitigation Measure
Incorrect data interpretation • Hardware Malfunction (sensor malfunction)	Non-clinical Performance Testing Labeling Training
Electrical Shock and Electrical Interference With Other Devices	Non-clinical Performance Testing
Weight Gain	Clinical Performance Testing Labeling

In combination with the general controls of the FD&C Act, the oral removable palatal space occupying device for weight management is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible for its intended use.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

    a) Mechanical testing must demonstrate that the device performs as intended for the labeled use life and does not create forces that result in movement of teeth and damage to teeth.

    b) Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.

    c) Software verification and validation must demonstrate that the device performs as intended.

    d) Battery testing must demonstrate that the device battery performs as intended.

3. Clinical performance testing must demonstrate the device performs as intended and must include an evaluation for choking.

4. Device labeling must address the following:

    a) Patient labeling must state:
        i. the clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

        ii. treatment must be offered in combination with a behavioral modification program;

        iii. instructions on how to use the device as intended; and

        iv. the use life of the device.

b) Physician labeling must state:
   i. the clinical benefit of weight management and/or weight loss as assessed by using percent total body weight loss;

   ii. treatment must be offered in combination with a behavioral modification program;

   iii. instructions on how to use the device as intended; and

   iv. the use life of the device.

5. Training must be provided to health professionals that include procedures for determining a patient's oral health status, instructions for making the palatal mold, and assessment of issues with the device that may require service by the manufacturer.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the oral removable palatal space occupying device for weight management they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mark J. Antonino, M.S. at (240) 402-9980.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health