DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 6, 2015

Somna Therapeutics, L.L.C.
James Miller
Vice President, Product Development & Regulatory Affairs
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Re: DEN130046
Reza Band® Upper Esophageal Sphincter (UES) Assist Device
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 874.5900
Regulation Name: External Upper Esophageal Sphincter (UES) Compression Device
Regulatory Classification: Class II
Product Code: PKA
Dated: November 22, 2013
Received: November 27, 2013

Dear Mr. Miller:

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 Reza Band® Upper Esophageal Sphincter (UES) Assist Device, a prescription device under 21 CFR Part 801.109 that is indicated for *patients 18 years and older to reduce the symptoms of laryngopharyngeal reflux (LPR) disease by reducing the regurgitation of stomach contents from passing through the upper esophageal sphincter. The device is worn by the patient when sleeping*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Reza Band® Upper Esophageal Sphincter (UES) Assist Device, and substantially equivalent devices of this generic type, into class II under the generic name, External Upper Esophageal Sphincter (UES) Compression Device.

FDA identifies this generic type of device as:

> **External Upper Esophageal Sphincter (UES) Compression Device:** An external upper esophageal sphincter (UES) compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux (LPR) disease.

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 November 27, 2013, FDA received your *de novo* requesting classification of the Reza Band® UES Assist Device into class I. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Reza Band® UES Assist 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 Reza Band® UES Assist Device indicated for "*patients 18 years and older to reduce the symptoms of laryngopharyngeal reflux (LPR) disease by reducing the regurgitation of stomach contents from passing through the upper esophageal sphincter. The device is worn by the patient when sleeping*" can be classified in class II with the establishment of special controls. 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**
Adverse tissue reaction	- Biocompatibility assessment
Risk of over-compression	- Clinical study - Labeling - Technical specifications
Device misuse/ incorrect fitting/ malfunctions	- Technical specifications - Clinical study - Labeling - Performance testing (mechanical integrity and shelf life testing)

In combination with the general controls of the FD&C Act, the External Upper Esophageal Sphincter (UES) Compression Device is subject to the following special controls:

1. The patient contacting components must be demonstrated to be biocompatible.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

   (A) Mechanical integrity testing (e.g., tensile strength testing, fatigue testing)
   (B) Shelf life testing

3. The technical specifications must include pressure measurement accuracy to characterize device performance.

4. Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

5. Labeling must include the following:

   (A) Appropriate warnings and precautions.
   (B) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events.
   (C) Detailed instructions on how to fit the device to the patient.
   (D) Instructions for reprocessing of any reusable components.

6. Patient labeling must be provided and must include:

   (A) Relevant warnings, precautions, and adverse effects/complications.
   (B) Information on how to correctly wear the device.
   (C) The potential risks and benefits associated with the use of the device.
   (D) Alternative treatments.
   (E) Reprocessing instructions.

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 not 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 External Upper Esophageal Sphincter (UES) Compression Device 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 Sunny Park at 301-796-7059.

Sincerely yours,

Jonette R. Foy -S

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