April 13, 2018

Somna Therapeutics, L.L.C.
James Miller
VP, Product Development & Regulatory Affairs
W175 N11081 Stonewood Dr.
Germantown, WI 53022

Re: K173934
Trade/Device Name: Reza Band, Reflux Band
Regulation Number: 21 CFR 874.5900
Regulation Name: External Upper Esophageal Sphincter (UES) Compression Device
Regulatory Class: Class II
Product Code: PKA
Dated: March 14, 2018
Received: March 16, 2018

Dear James Miller:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173934

Device Name
Reza Band, Reflux Band

Indications for Use *(Describe)*
The Reza Band and the Reflux Band are for people 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 devices are worn by the user while sleeping.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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K173934 – 510(k) Summary

510(k) Summary for the Reflux Band™ and Reza Band® provided in accordance with 21 CFR 807.92

510(k) Owner:	Somna Therapeutics, LLC W175 N11081 Stonewood Drive Germantown, WI 53022 Phone: (262) 345-5553 Fax: (262) 345-5618
Name of Contact Person:	James Miller
Date of Summary Preparation:	December 21, 2017
Device Common Name:	External upper esophageal sphincter (UES) compression device
Device Trade/ Proprietary Name:	Reflux Band™, Reza Band®
Classification Name:	External upper esophageal sphincter (UES) compression device (21 CFR 874.5900, Product Code PKA)
Predicate Device:	Reza Band ® Upper Esophageal Sphincter (UES) Assist Device (DEN130046)
Device Description:	The Reza Band and Reflux Band are proposed for over the counter (OTC) use. The proposed devices are non-invasive and non-sterile worn by the user while sleeping. As with the predicate device (Reza Band), the proposed Reza Band and Reflux Band were designed as a treatment for LPR symptoms. The mode of operation of these devices is to provide slight external pressure, typically in a range of 20-30 mmHg, at the cricoid cartilage region. This external pressure increases the luminal pressure within the upper esophageal sphincter (UES). It has been shown that when the UES is subjected to the increased external pressure, it reduces stomach contents from coming up into the larynx, pharynx and lungs. The user positions the device around their neck. For the Reflux Band, the user uses an application (App) installed on an iOS or Android mobile device to fit the Reflux Band to the desired externally applied pressure. The electronics of the Reflux Band have been incorporated into its cushion (SmartCushion) so that the Reflux Band can interact with the App. For the Reza Band, the user utilizes the accessories External Manometer and Pressure Sensor to properly fit the device. A typical range is also 20-30mmHg of applied pressure. The components of the Reflux Band and Reflux Band are identical (except for the electronics of the cushion as noted above) and consist

	of a Cushion, Comfort Band, Frame, Comfort Dial and Clasp.
Intended Use:	The Reza Band and the Reflux Band are for people 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 devices are worn by the user while sleeping.
Comparison to Predicate Device:	The intended use is substantially equivalent to the predicate device. The Reflux Band brand was added and the word "patient" was changed to "people" and "user" to reflect the proposed over the counter (OTC) application. The components for the Reza Band and the Reflux Band are identical except for the added electronics in the SmartCushion of the Reflux Band. The method of applying external pressure at the cricoid, device application, use life, shelf life, user population, biocompatibility, mechanical strength, materials and standards compliance are identical or substantially equivalent.
Non-Clinical Performance Data:	Non-Clinical performance data to support substantial equivalence included: • Testing to IEC 60601-1 • Testing to IEC 60601-1-2 • Software Verification and Validation • Bench Testing for Manometer Accuracy • Shelf Life Testing
Clinical Performance Data:	Clinical performance testing to support substantial equivalence included: • Usability testing • Comprehension testing of a tool commonly used for the population with LPR symptoms is the Reflux Symptom Index (RSI).
Conclusion of Clinical and Non-Clinical Data:	Based on the results of Clinical and Non-Clinical data, the Reflux Band and Reza Band devices are substantially equivalent to the predicate (DEN130046), and can be used safely and effectively as OTC devices.