DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 9, 2016

Somnics Inc.
Tsung-Min Hsieh
Manager, QA & RA
5F, No. 22, Sec. 2, Sheng Yi Rd., Hsinchu Science Park, Zhubei City
Hsinchu County
TAIWAN

Re: K152660
Trade/Device Name: HypnosPad
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: Class II
Product Code: LRK
Dated: September 30, 2016
Received: October 3, 2016

Dear Tsung-Min Hsieh:

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" (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 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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 below.

510(k) Number *(if known)*

Device Name
HypnosPad

Indications for Use *(Describe)*
The HypnosPad of mandibular advancement devices is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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.

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510(k) Summary

I. SUBMITTER

Company Name: Somincs Inc.
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Summary Preparing Date: October 11, 2016

II. DEVICE

Name of Device: HypnosPad, Model HP01
Common or Usual Name: Anti-Snoring / Sleep Apnea Device
Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570)
Device Classification: II
Product Code: LRK
Prior Submission: no prior submissions for the same device

III. PREDICATE DEVICE

SomnoGuard, K061688
This predicate has not been subject to a design-related recall in US.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

- HypnosPad (HP01) is a home-use mouthpiece and indicated for the treatment of night-time snoring. It is suitable for mild to moderate obstructive sleep apnea (OSA) patients in adults.

- The accessories of HyponsPad are a storage box and a spatula.
- The device is made by thermoflexible and biocompatible material.
- The usage method of HyponsPad is custom fit after hot water bathing.
- The duration of HypnosPad is about 8-10 hours contacting in patient's oral cavity.
- The HyponsPad is intended for holding the mandible in a protruded position thus maintaining the airway open during sleep.
- The HypnosPad will be used the spatula help to operate the device during boil and bite process.
- The HypnosPad will be stored in the storage box.

V. INDICATION FOR USE

The HypnosPad of mandibular advancement devices is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed "HypnosPad" and the predicate are intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. Their indications for use, fundamental design, and technological characteristics are also comparable, as listed in the following table:

Device	**HypnosPad (Model: HP01) – The Subject**	**Predicate Device SomnoGuard in SomnoGuard Series**	**Comparison**
Intended Use & Indications for Use	Treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Identical
Mechanism of Action	Extend the lower jaw, thereby opening the upper airway and reducing snoring and	Extend the lower jaw, thereby opening the upper airway and reducing snoring and	Identical

	the breathing arrests due to obstructive sleep apnea.	the breathing arrests due to obstructive sleep apnea.	
OTC/Prescription Use	Prescription Use	Prescription Use	Identical
Device Composition	MAD Device, Spatula Storage box	MAD Device Spatula Storage box	Identical
Single Patient	Single patient	Single patient	Identical
Multiple Use	Multiple use	Multiple use	Identical
Treatment Time	Everyday overnight	Everyday overnight	Identical
Where Used	At home or clinic setting(Sleep Laboratories)	At home or clinic setting(Sleep Laboratories)	Identical
Design Concept	One piece design	One piece design	Identical
	Ready-to-Use	Ready-to-Use	
	Upper and low trays	Upper and low trays	
Personal Interface of Custom Fabricated	Boil and bite fitting for Personalized products as a single patient multiple use	Boil and bite fitting for Personalized products as a single patient multiple use	Identical
Design – Patient Contacting Materials	Thermoplastic elastomer	Thermoplastic elastomer	Purpose: Identical; Technology/spec: Difference, there is no additional risk based on material property evaluation (Appendix K), and Performance Testing Report for Fitting Process and Mechanical Strength (Appendix F).
Adjustable	Re-mold with lower jaw extended but not in mechanism adjust.	Re-mold with lower jaw extended but not in mechanism adjust.	Identical

Material Thermal properties	Optimal thermoplastic condition is large than 67˚C	Optimal thermoplastic condition is large than 60˚C	Purpose: Identical; Technology/spec: Difference, there is no additional risk based on Thermal Property Test Report (Appendix H).
Human Factors	Use during sleep period. User operates boil and bite fitting at first time to use.	Use during sleep period. User operates boil and bite fitting at first time to use.	Purpose: Identical Technology/spec: Difference, there is no additional risk based on usability test (Appendix D).
Design – Oral appliance size and outward	52mm x62.5mm x 20.5mm	44.5mm x 63mm x25.5 mm	Purpose: Identical Technology/spec: Difference, there is no additional risk based on usability test (Appendix D).
	Fillet cushion	NA	
	Lip seal curve	NA	
Design – Mandibular Advancement Range	Up to 10 mm Limited mandibular advancement. Patients with OSA should be able to extend their lower jaw forward at least 7mm	Limited mandibular advancement. Patients with sleep apnea should be able to extend their lower jaw forward at least 7mm	Purpose: Identical; Technology/spec: Difference, there is no additional risk based on Performance Testing Report for Fitting Process and Mechanical Strength (Appendix F).
Sterility Requirement	Non-sterile	Non-sterile	Identical
Biocompatibility	Biocompatibility testing based on ISO 10993-1	Biocompatibility testing based on ISO 10993-1	Identical

Based on the testing results and relative technical information, the new device through these performance testing is substantially equivalent to the predicate.

VII. PERFORMANCE DATA

This device conforms to the standards and testing listed below:

- ISO 10993-1:2009: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010: Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Usability test (Based on IEC 62366:2007: Medical devices – Application of usability engineering to medical device)
- Bench test for performance for fitting process and mechanical strength
- Material property evaluation
- Thermal property test
- Comparative testing was done between the new device and the noted predicate device for the material property evaluation, thermal property and the fitting process and mechanical strength. These performance data of the new device are demonstrated that the new device performed as well as the noted predicate.

Summary:
Based on the results of performance testing, HypnosPad was found to be as safe and as effective as the predicate.

VIII. CONCLUSION

The indication for use for the subject device is identical to the predicate device. The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness. The performance data provided demonstrate that the device performs as intended and is as safe and as effective as the predicate device.