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 1, 2016

Firma Ingemarsson
c/o Mr. Poul Schmidt-Andersen
Danish Medical Devices Consulting APS
Doktor Mundtsvej 9B
Farum, 3520
DENMARK

Re: K160531
Trade/Device Name: Noiselezz®
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: July 10, 2016
Received: July 26, 2016

Dear Mr. Poul Schmidt-Andersen:

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)
K160531

Device Name
Noiselezz®

Indications for Use (Describe)

Noiselezz® is intended for the treatment of nighttime snoring 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.

510(k) Summary

807.92(c)

Submitter

807.92(a)(1)

Company Name	Firma Ingemarsson
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Contact person	Natashia Ingemarsson-Matzen

Device Information

807.92(a)(2)

Device Name	Noiselezz®
Common Name	Noiselezz®
Product Code	LRK
Registration Number	21 CFR 872.5570
Classification	Class II
Classification Panel	Dental

Predicate Device

807.92(a)(3)

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Sleeping Well LLC	ZQuiet®	K090503

Device Description

The Noiselezz® Mouthpiece is an Anti-Snoring device consisting of

- Two trayed plates fitted in front and between the upper and lower teeth and gums and integrated with each other with the same material as the upper and lower plates.
- The device is made of Thermoplastic elastomer
- May be used as supplied

Device Intended Use

807.92(a)(5)

Noiselezz® is intended for the treatment of nighttime snoring in adults.

Comparison of Proposed Device vs. Predicate

807.92(a)(6)

	Subject Device	Predicate device
Device name	**Noiselezz®**	**Zquiet®**
510(k) number	K160531	K090503
Device Classification	Class II	Class II
Classification name	Anti-snoring device	Anti-snoring device
Regulation number	21 CFR 872.5570	21 CFR 872.5570
Regulation panel	Dental	Dental
Product code	LRK	LRK

	Subject Device	Predicate device
Device use		
Indication for Use	Noiselezz® is intended for the treatment of nighttime snoring in adults.	The ZQuiet Anti-Snoring device is intended for the treatment of nighttime snoring in adults.
Target population	Adults	Adults
Where used	Home or sleep laboratories	Home or sleep laboratories
Prescription	Prescription device	Prescription device
Intended as an intraoral device	Intended as an intraoral device	Intended as an intraoral device
Intended to reduce snoring or help alleviate snoring	Intended to reduce snoring or help alleviate snoring	Intended to reduce snoring or help alleviate snoring
Multiple use	Indicated for singe patient multi use	Indicated for singe patient multi use
Placement of device	Placed in patient mouth each evening	Placed in patient mouth each evening
Cleaning of device	Cleaned daily	Cleaned daily
Patient Use		
Breathing	Permits patient to breathe through mouth	Permits patient to breathe through mouth
Cleaning	Cleaned daily	Cleaned daily
Placement	Placed in user's mouth each evening	Placed in user's mouth each evening
Removal	Easily removed from the mouth	Easily removed from the mouth
Materials		
Non-Sterile	Non-Sterile	Non-Sterile
Components	One piece design	One piece design
Molding	Upper and lower trays fitted to patient by heating material	Upper and lower trays fitted to patient by heating material
Occlusal notches	None Occlusal notches	Occlusal notches
Saw-tag mechanism at the occlusal surface closest to the hinge	None saw-tag mechanism at the occlusal surface closest to the hinge	Saw-tag mechanism at the occlusal surface closest to the hinge
Biocompatibility		
Test method of base material	• ISO 10993-5 (Cytotoxicity) • ISO 10993-4 (Hemocompatibility) • USP 32, NF 27 (88) Biological Reactivity Tests, In Vivo	ISO 10993

Substantial Equivalence Discussion

The reason for not adding the occlusal notches is the desire to keep the design as simple as possible. This goes for the saw-tag mechanism too. Furthermore, those extra elements on the occlusal surface of the device increases the risk of accumulation of debris, which might dry in and deteriorate the cleaning process.

The base material is especially intended for exposure to tissue when used for medical tubing and contact to the mucosal membrane.

Nonclinical and Clinical Test

807.92(b)

Safety and Effectiveness

Biocompatibility

The material has been cleared with respect to FDA Unspecified Rating, ISO 10993 Part 5 (Cytotoxicity). ISO 10993 Part 4 (Hemocompatibility) and USP Class VI.

Furthermore, FDA under DMF #10824 has registered the material

Non-Clinical Performance Data

Physical properties testing of base material has been conducted for the following and the associated standards:

Physical property	Standard/Test Method
SPECIFIC GRAVITY	ASTM D792 (ISO 2781)
SHORE A HARDNESS	ASTM D2240 (ISO 868)
TENSILE STRENGTH	ASTM D412-Die C (ISO 37)
ELONGATION	ASTM D412-Die C (ISO 37)
VISCOSITY	ASTM D3835 (ISO 11443
COLOR	-

Noiselezz® Anti-Snoring Device has been evaluated for safety through shelf-life test of the finished device and in vitro tests and animal safety studies of base material.

Conclusion

807.92(b)(3)

Noiselezz® Anti-Snoring Device is substantially equivalent to the predicate device because they share the same intended use and a similar design.