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

August 13,2015

ResMed Corp.
Larissa D'Andrea
Director, Government and Regulatory Affairs
9001 Spectrum Center Blvd.
San Diego, CA 92123

Re: K143623
Trade/Device Name: Narval Brux
Regulation Number: None
Regulation Name: Mouthguard
Regulatory Class: Unclassified
Product Code: MQC
Dated: July 16, 2015
Received: July 17, 2015

Dear Ms. D'Andrea:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Narval Brux**

Indications for Use:

The Narval Brux is intended for protection of teeth and restorations from the forces of bruxism.

Prescription Use ____**X**_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Page 1 of__1_

510(k) SUMMARY

K143623

Date Prepared	13 July 2015
Submitter	Ms. Larissa D'Andrea Regulatory Affairs Manager
Official Contact	Ms. Larissa D'Andrea Regulatory Affairs Manager 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836-6837
Device Trade Name	Narval Brux
Device Common Name	Mouthguard
Classification	Unclassified
Product Code	MQC
Predicate Devices	SomnoMed Inc., SomnoBrux® Splint(s), K102909

Description

The Narval Brux is a removable intraoral device used for protecting teeth and restorations against the forces of bruxism. It consists of patient-specific splints that fit separately over the upper or lower teeth. The design of the splints is dependent on the patient needs.

The device functions as a protective barrier for teeth and restorations by creating physical separation between posterior occlusal surfaces and/or anterior incisal edges which will prevent tooth damage caused by grinding, bruxing and may help alleviate jaw and muscle pain.

The device is customized for each patient based on the clinician prescription.

Intended Use

The Narval Brux is intended for protection of teeth and restorations from the forces of bruxism.

Technological Characteristics

Based on the comparative analysis of technological characteristics, Narval Brux and SomnoBrux are substantially equivalent. Both are patient-specific devices which cover posterior occlusal surfaces and/or anterior incisal edges and act as protective barriers for teeth and restorations from the effects of bruxism. Any minor design and material differences do not affect safety and performance.

	New Device:	Predicate Device: SomnoBrux Splint(s) (K102909) SomnoMed Inc.
Indication For Use Statement	The Narval Brux is intended for protection of teeth and restorations from the forces of bruxism.	The SomnoBrux Splints are used for the protection of teeth and restorations from the forces of Bruxism.
Materials	Nylon	Acrylic
Prescription / Over the Counter	Prescription	Prescription
Single Use / Reusable	Reusable	Reusable
Fixed / Removable	Removable	Removable
Sterile / Non-Sterile	Non-sterile	Non-sterile

Summary of Non-Clinical and Clinical Testing

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included: biocompatibility (cytotoxicity, sensitization, and irritation per ISO 10993), software validation, cleaning validation, and performance testing (static compression). The non-clinical data included in this submission demonstrate substantial equivalence to the predicate device K102909.

Clinical data were not submitted in this premarket notification.

Substantial Equivalence Conclusion

Based on the testing performed, including biocompatibility, software validation, cleaning validation, and performance testing, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Narval Brux are assessed to be substantially equivalent to the predicate device.