5. 510(k) SUMMARY

[As required by 21 CFR 807.92]

Date Prepared	27 October, 2011
Submitter	Ms. Tracey Bullivant, Regulatory Affairs Manager
Official Contact	Mr. David D'Cruz V.P., US Medical & Regulatory Affairs 9001 Spectrum Centre Blvd San Diego CA 92123 USA Tel: (858) 836 5984
Device Trade Name	Narval CC™
Device Common Name/Classification Name	Mandibular repositioning device;
Classification	21 CFR 872.5570 (Class II)
Product	LQZ
Predicate	Somnomed MAS RxA (K050592) Frantz Elastic Mandibular Advancement (EMA) Appliance (K971794)
Description	The Narval CC is a removable intraoral device used for treating snoring and sleep apnea. It consist of two custom fabricated splints that fit separately over the upper and lower teeth and engage by means of adjustable rods. The device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving his/her ability to exchange air and reducing the tendency to snore. The device is custom made for each patient and has an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting.
Intended Use	The Narval CC is intended to reduce or alleviate snoring and mild to moderate obstructive sleep annea (OSA) in adults.
Technological Characteristics	The following table displays the differences and similarities between the new Narval CC device and two other previously marketed (predicate) devices. Equivalence is based on similarities in intended use, materials of construction, design, and operating principles, as summarized in the table on the following page.

Feature	Narval CC	Somnomed MAS RxA (K050592)	Frantz Elastic Mandibular (EMA) Appliance (K971794)
Intended Use	To reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	To reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where advancement of the mandible and opening the bite can increase the patient's airspace.
Materials of construction	Made from polymers (Polyamide).	Made from acrylic and stainless steel.	Made from thermoplastic and polymers.
Design	Two customized splints that fit separately over the upper and lower teeth inside the mouth. The lower splint contains a triangular protrusion, allowing the splints to engage by means of interlocking rods on the sides.	Two customized splints that fit separately over the upper and lower teen inside the mouth. The lower splint contains a fin-shaped protrusion, allowing the splints to engage by means of adjustable lugs on the sides.	Two customized splints that fit separately over the upper and lower teeth inside the mouth. The splints engage each other by means of retention hooks and interlocking elastic straps.
Principle of operation/means of mandibular advancement.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position.	Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position.	Adjustment of the relative position of the splints by the use of elastic force pulls the mandible forward and maintains advancement thus enlarging the airway. The vertical opening of the jaw is not fixed in a single position.
Fixed/ removable	Removable	Removable	Removable
Adjustment	Adjusted via the use of interlocking rods placed on the sides of the splints. The shorter the rod, the further the mandible is advanced.	Adjusted via the use of interlocking lugs and wings placed on the sides of the splints.	Adjusted via the use of interlocking elastic straps placed on the sides of the splints. The shorter the strap, the further the mandible is advanced.
Supplied sterile/non sterile	Non sterile	Non sterile	Non sterile
Single use/reusable	Reusable	Reusable	Reusable
Prescription/ OTC	Prescription only	Prescription only	Prescription only

Substantial Equivalence Conclusion The new device, the Narval CC, is considered to be substantially equivalent to the predicate devices based on the following:

- it has essentially the same intended use and is indicated for the same user population;
- it has equivalent technological characteristics to the predicates;
- it does not raise new questions of safety and effectiveness;
- it is at least as safe and effective as the predicative devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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ResMed SAS
C/O Mr. David D'Cruz
VP, U.S. Medical and Regulatory Affairs
ResMed Corp.
9001 Spectrum Center Blvd.
San Diego, CA 92123

Re: K113201
Trade Name: Narval CC™
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Codes: LQZ
Dated: October 27, 2011
Received: October 31, 2011

Dear Mr. D'Cruz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113201

Device Name: **Narval CC™**

Indications for Use:

The Narval CC™ is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (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)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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