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

March 31, 2016

Sicat GmbH& Co. KG
Dr. Manfred Breuer
Head of Quality Management and Regulatory Affairs
Brunnenallee 6
Bonn, North Rhine- Westphalia 53177
GERMANY

Re: K153291
Trade/Device Name: SICAT OPTISLEEP
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 Code: LRK, LQZ
Dated: February 18, 2016
Received: February 19, 2016

Dear Dr. Breuer:

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,

Tina Kiang -S

for 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): K153291

Device Name: SICAT OPTISLEEP

Indications for Use:

In adult population
- To reduce or alleviate snoring
- To reduce or alleviate mild to moderate obstructive sleep apnea (OSA)

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k)_____

# 510(k) Summary
# for
# SICAT OPTISLEEP

**Content and format as required by section 21 CFR 807.92**
(***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm***)

## 1. SUBMITTER/510(K) HOLDER

SICAT GmbH & Co. KG
Brunnenallee 6
53177 Bonn
Germany

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|---|---|
| Establishment Registration Number: | 3006098230 |
| Telephone: | +49 228 854697-82 |
| Primary Contact: | Mr. Dr. Manfred Breuer |
| Secondary Contact: | Ms. Dr. Petra Benkel |
| Date Prepared: | Nov. 12th, 2015 |

## 2. DEVICE NAME AND DEVICE CLASSIFICATION

| | |
|---|---|
| Proprietary Name: | SICAT OPTISLEEP |
| Common/Usual Name: | Intraoral device for snoring and obstructive sleep apnea |
| Classification Name: | Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea |
| Regulation Number: | 21 CFR 872.5570 |
| Classification Class: | 2 |
| Product Code: | LRK |
| Secondary Product Code: | LQZ |

## 3. PREDICATE DEVICES

- Primary Predicate: Narval CC (K113201)
- Reference Predicate: SomnoDent Classic (K050592)

## 4. DEVICE DESCRIPTION

SICAT OPTISLEEP is a pure hardware device. It is an oral appliance and will be manufactured by the SICAT dental laboratory to and on the order of a dentist, physician or licensed practitioner. Each appliance is customized for patients.

SICAT OPTISLEEP is fitted on the maxillary and mandibular arch covering all teeth. It consists of two main parts (upper and lower arch each) that are interconnected by exchangeable

connectors. This 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 the ability to exchange air during sleep by reducing mechanical obstructions of the airway. Further this results in lower tendency to snore. The device has an adjustment mechanism, achieved by exchangeable connectors of different length, to adjust the mandibular advancement to be set by the dentist or physician at the time of fitting.
The SICAT OPTISLEEP will be worn only during the sleep. The device will be used before replacement up to two years.

### 4.1 Material / Physical Properties

The main parts of the device are made of Polymethylmethacrylate. The exchangeable connectors are made of Polyamide.

## 5. Indications for Use

In adult population
- To reduce or alleviate snoring
- To reduce or alleviate mild to moderate obstructive sleep apnea (OSA)

## 6. Device Comparison Table

The following table shows a summary of the intended use, technological characteristics, design and function of SICAT OPTISLEEP and the predicate devices.

| | **SICAT OPTISLEEP** | **Reference Predicate**<br><br>**Somnomed MAS RxA (K050592)**<br><br>**Last Brand Name: SomnoDent Classic** | **Primary Predicate**<br><br>**Narval CC (K113201)** |
|---|---|---|---|
| **Regulation Information** | | | |
| Product Code | LRK | LRK | LQZ |
| Second Product Code | LQZ | - | - |
| Classification Regulation | 21 CFR 872.5570 | 21 CFR 872.5570 | 21 CFR 872.5570 |
| Device Class | 2 | 2 | 2 |
| Device Classification Name | Device, Anti-Snoring | Device, Anti-Snoring | Device, Jaw-Repositioning |
| Common / Usual Name | Intraoral device for snoring and obstructive sleep apnea. | Mandibular advancement device | Mandibular repositioning device |
| **Manufacturer** | | | |
| Name | SICAT GmbH & Co. KG | SomnoMed Inc. | ResMed |
| Address | Brunnenallee 6,<br>53177 Bonn,<br>GERMANY | SomnoMed Inc., 20 Clarke Street Crows Nest,<br>NSW 2065, Australia | ResMed SAS<br>ResMed Corp.<br>9001 Spectrum Center Boulevard, San Diego, |

| | SICAT OPTISLEEP | Reference Predicate<br><br>Somnomed MAS RxA (K050592)<br><br>Last Brand Name: SomnoDent Classic | Primary Predicate<br><br>Narval CC (K113201) |
|---|---|---|---|
| | | | CA 92123, USA |
| **Indications for Use** | | | |
| | In adult population<br>• To reduce or alleviate snoring<br>• To reduce or alleviate mild to moderate obstructive sleep apnea (OSA) | To reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. | The Narval CC is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults. |
| **Device Description** | | | |
| Design | SICAT OPTISLEEP 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 connectors. 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 during sleep. The device is customized and patient specific 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. | The Somnomed MAS RxA is an intraoral device used for treating Snoring and Sleep Apnea. It consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs. The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. The device is custom made for each patient and has the adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. | 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. |
| Basic design | mandibular repositioner | mandibular repositioner | mandibular repositioner |

| | SICAT OPTISLEEP | Reference Predicate<br><br>Somnomed MAS RxA (K050592)<br><br>Last Brand Name: SomnoDent Classic | Primary Predicate<br><br>Narval CC (K113201) |
|---|---|---|---|
| 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 limited to a single position. | Adjustment of the relative position of the splints guides the mandible forward and maintains advancement thus enlarging the airway.<br>The vertical opening of the jaw is not limited to 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. |
| Adjustments | Adjusted via the use of interlocking connectors of different length placed on the sides of the splints, the longer the connector, 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 rods placed on the sides of the splints, the shorter the rod, the further the mandible is advanced. |
| **Properties** | | | |
| Material | • Acrylic (Polymethyl-methacrylate, PMMA)<br>• Polyamide<br>• | • Acrylic<br>• Stainless steel | • Polyamide |
| Reusable by same patient | Yes | Yes | Yes |
| **Method of Manufacture** | | | |
| | Milling at SICAT dental laboratory with CAD/CAM technology | Dental laboratory | Made by selective laser sintering of a polymer material in a dental laboratory with CAD/CAM technology |
| **Cleaning, Maintenance, Biocompatibility** | | | |
| Cleaning | Toothbrush with water; mild detergent; partial denture cleaner without oxygen | Toothbrush with water; mild detergent; partial denture cleaner without active oxygen by Somnomed | Toothbrush with water; sonic cleaner; Narval cleaner |
| Maintenance | Regular check up with dental medical professional | Regular check up with dental medical professional | Regular check up with dental medical professional |

| | SICAT OPTISLEEP | Reference Predicate<br><br>Somnomed MAS RxA (K050592)<br><br>Last Brand Name: SomnoDent Classic | Primary Predicate<br><br>Narval CC (K113201) |
|---|---|---|---|
| | | | |
| Bio-compatible | Yes | Yes | Yes |
| **Miscellaneous** | | | |
| Design | Customized | Customized | Customized |
| Use | Only during sleep | Only during sleep | Only during sleep |
| Removable | Yes | Yes | Yes |
| Supplied sterile | No | No | No |
| Prescription only | Yes | Yes | Yes |
| Target Population | Persons in the age of 18 years and older | Persons in the age of 18 years and older | Persons in the age of 18 years and older |

## 7. NON-CLINICAL PERFORMANCE TESTING AND VERIFICATION AND VALIDATION ACTIVITIES

For SICAT OPTISLEEP, verification and validation activities were performed, in accordance with the following guidance and standards:

| Standard | Title |
|---|---|
| ISO 15223-1 Second Edition:2012 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements |
| ISO 14971 Second Edition:2007 | Medical devices – Application of risk management to medical devices |
| AAMI / ANSI / IEC 62366:2007/(R)2013 | Medical devices - Application of usability engineering to medical devices |
| ISO 7405 Second Edition: 2008 + Amd. 1:2013 | Dentistry – Evaluation of biocompatibility of medical devices used in dentistry |
| ISO 10993-1 Fourth Edition:2009 | Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system |
| ISO 10993-5 Edition 3 2009-06-01 | Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity |
| ISO 10993-12 Fourth Edition 2012-07-01 | Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials (Biocompatibility) |
| ISO 10993-17:2002 | Biological evaluation of medical devices -- Part 17: Establishment of |

| | |
|---|---|
| | allowable limits for leachable substances |
| ISO 10993-18 First Edition 2005-07-01 | Biological Evaluation Of Medical Devices -- Part 18: Chemical Characterization Of Materials |

**Guidance**

- Device Labeling Guidance, March 8, 1991 (G91-1)
- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: July 18, 2000
- Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Document issued on: November 12, 2002
- Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Among others the following verification and validation activities were performed

- evaluation of biocompatibility
- usability testing
- bench testing of compliance with specifications and handling

## 8. CONCLUSION

Based on the information and supporting documentation provided in this premarket notification, SICAT OPTISLEEP is considered to be substantially equivalent in design, material type, technological characteristics and function to the predicate devices Narval CC (K111066) and SomnoDent Classic (K102909).

The indications for use and patient populations of SICAT OPTISLEEP are the same for SICAT OPTISLEEP and the predicate devices.

All three devices are devices for a specific patient and are manufactured to and on the order of a dentist, physician or licensed practitioner. All devices use trays made of plastics (polyamide or acrylic). The adjustment mechanism for the mandibular advancement differs only slightly.

Any minor differences between SICAT OPTISLEEP and the predicate devices do not raise new questions concerning safety and effectiveness.