

Dedicated to
Customer Value

K061688

TOMED

SEP - 8 2006

CV

Dr. Toussaint GmbH

TOMED Dr. Toussaint GmbH • Lindberghstr. 3a • D - 64625 Bensheim

TOMED Dr. Toussaint GmbH
Medical Products
Lindberghstr. 3a
D - 64625 Bensheim
Germany

Tel.: +49-6251-98 33 44
Fax: +49-6251-98 33 45
eMail: w.toussaint@tomed.com
<http://www.tomed.com>

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1. *Submitter's Name:* TOMED Dr. Toussaint, GmbH
2. *Address:* Lindberghstr. 3A
Bersheim, Germany D-64625
3. *Telephone:* 49-6251-983344
4. *Contact Person:* Dr. Winfried Toussaint
5. *Date Prepared:* May 1, 2006
6. *Registration Number:* Pending

B. Device

1. *Name:* SomnoGuard Series (SomnoGuard, 2.0, AP, and AP Pro)
2. *Trade Name:* Anti-Snoring / Sleep Apnea Device
3. *Common Name:* Anti-Snoring / Sleep Apnea Device
4. *Classification Name:* Device, Anti-Snoring
5. *Product Code:* LRK
6. *Class:* II
7. *Regulation Number:* 872.5570

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C. Identification of Legally Marketed Devices

1. *Names:* QuietKnight, Silencer (Version I. and II.), TheraSnore, TAP, Silencer, MDSA)
2. *K Number:* K962516, K033822, 033823, 926382, 972061, 954530, 042161
3. *Date Cleared:* January 24, 1997, February 6, 2004, February 6, 2004, July 8, 1993, August 21, 1997, October 30, 1995, October 27, 2004

D. Description of the Device

The whole family of SomnoGuard mandibular advancement devices is used for treating snoring and obstructive sleep apnea. The main effect of all appliances is the advancement of the lower jaw, thereby opening the upper airway and reducing snoring and the breathing arrests due to obstructive sleep apnea.

SomnoGuard and its minor modification SomnoGuard 2.0 are one-part appliances manufactured from thermoflexible copolymeric material. SomnoGuard can be fitted without the need of taking a patient's dental impressions as a prerequisite to construct the ready-to-use device. To prepare fitting of the appliance it is necessary to heat the appliance in hot water that has been boiled for around 30 seconds. Thereafter, when the device was removed from the hot water and has cooled down for about 10 seconds, a physician or his or her trained staff inserts the device into the mouth of the patient, thereby first the lower jaw into the lower arch, then the upper jaw into the upper channel of the device. The patient then puts forward his or her lower jaw commonly at normal bite conditions to approximately half the maximum extension possible, with the plastic still warm and moldable, and then firmly bites the plastic. When doing this, patient sucks in while closing the mouth and pressing the tongue against the inner surface of the front teeth. In parallel, doctor presses his or her fingers on the outer walls of the mouthpiece to

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make sure that the appliance is properly molded. After fixing the bite impression by cold water the fitting is finished. To raise the molar bite when necessary (e.g. in case of a "deep-bite") the SomnoGuard pack contains a filler strip made of the same copolymeric material as the appliance itself. To raise the bite the strip is heated in hot water and then stucked in parts into the channel of the appliance.

SomnoGuard 2.0 differs from SomnoGuard by a slightly thicker molar biting zone (i.e. 1.5 mm on each site of the biting plate) and an increase of the molar side walls of 1.0 mm. As opposed to the SomnoGuard time consuming use of the filler strip can thus be avoided with the SomnoGuard 2.0 in patients with a "deep bite".

Both SomnoGuard and - 2.0 contain a hole in the front area, large enough for emergency breathing. Both one-part appliances are primarily considered by sleep specialists and dentists for short-term use up to about one year or as a first-line screening devices to find out whether patients suffering from snoring and / or obstructive sleep apnea (OSAS) respond to oral appliance therapy at all what can't be predicted for any appliance available in the marketplace prior to its usage. Thus in case of no therapeutic effect larger investments for the much more expensive custom dental lab made appliances can be avoided.

The SomnoGuard product family comprises another "boil-&-bite" member i.e., SomnoGuard AP (AP = Adjustable Positioner), a two-part infinitely adjustable (titratable) appliance enabling a protrusion of up to 12 mm, allowing lateral lower jaw movement and breathing through the mouth whenever needed. The device consists of two independent trays with each a thermoplastic body, and both parts linked to each other by a coupling protrusion mechanism. The outer tray shells consist of solid clear and transparent medical grade polycarbonate. The inner lining which accommodates the teeth impressions is made of a thermoplastic copolymer as it is similarly used with the SomnoGuard® one-part appliances. After the oral appliance is heated in a hot water bath its thermoplastic body moulds easily to the teeth and jaws allowing any medical doctor to fit very easily the device chair side.

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An adjusting screw made of stainless steel allows the anterior adjustment of the lower tray against the upper tray between 0 and about 12 mm or even more depending on the length of the screw used. The adjustment is only possible extra-orally and when the upper and lower trays are disassembled. Disassembling both trays is also necessary for cleaning.

By using the scale on both sides of the thread you can exactly control the adjustment with an accuracy of about 0.5 mm. Upper and lower trays can be moved laterally.

The highly cost-effective device is considered for medium term use up to two years

All "boil-&-bite" appliances are simple to fit by dentists and other medical specialists, taking about 10 minutes and not requiring any special tools. Since with not any existing oral appliance available in the marketplace treatment outcome can be predicted for sure as already mentioned earlier, it always makes sense from a cost and economical point of view to start treatment at first with cheaper boil & bite devices before doing a larger investment for the fabrication of custom made dental appliances such as the SomnoGuard AP Pro which will be described thereafter.

The currently last family member is the SomnoGuard AP Pro, an always dental lab made two-part titratable mandibular adjustable positioner with its development closely related and derived from the preceding development of the AP appliance. The SomnoGuard® AP Pro can easily be constructed from common acrylic/elastomeric thermoform dental materials in any dental lab after taking impressions of the lower and upper jaws and producing plaster models. The components used to connect the upper and lower trays of the dental appliance and enable the infinite advancement of the lower jaw are made from stainless steel. The component's technology is based on the preceding development of the SomnoGuard® AP. The components are very durable, more or less indestructible, inexpensive and can most often be reused when the oral appliance has to be remade for some reason. The cost-effectiveness of the SomnoGuard AP Pro and the fact that the device can easily be constructed by any dental lab using standard lab equipment are

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considered as key benefits compared to the more expensive competitive dental appliances.

All stainless steel components of the two-part appliances correspond to the material no.1.4301 (AISI-no. 304) resp. to DIN EN 10088-1. The chemical composition is commonly as follows:

C ≤ 0,07 weight%, Cr 17,0 - 19,5 w%, Ni 8,0 - 10,5 w% und N ≤ 0,11 w%, Si ≤ 1,0 w%, Mn ≤ 2,0 w% .

E. Intended Use Statement

Indicated use: the SomnoGuard series of mandibular advancement devices is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSAS) in adults.

F. Technological Characteristics Summary

Similarities between the devices are the following:

- Indications for Use
- Single Patient
- Multi-Use
- Prescription Device
- Non-Sterile
- Custom Fabricated (Fit)
- Adjustable
- Environment – Home/Sleep Laboratories
- Components
- Two Trays (Upper and Lower)
- Materials
- Removable

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The differences are minor and do not have a significant effect on the safety or effectiveness of the SomnoGuard Series.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Winfried Toussaint
Tomed Dr. Toussint GmbH
Medical Products
Lindberghstr. 3A
D-64625 Bensheim
GERMANY

Re: K061688

Trade/Device Name: Anti-Snoring/Sleep Apnea Device
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
Dated: July 28, 2006
Received: August 10, 2006

Dear Mr. Toussaint:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K061688

Indications for Use

510(k) Number (if known): *K061688*

Device Name: SomnoGuard Series

Indications for Use:

The SomnoGuard Series of mandibular advancement devices (SomnoGuard,2.0,AP and AP Pro) is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in adults.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

Concurrence of CDRH Office of Device Evaluation (ODE)



(Print Name)
Susan Quinn, MD
Department of Anesthesiology, General Hospital,
FDA Region 10, Division of Anesthesia, Dental Devices

(510(k) Number): K061688