K980952

JUN 1 1998

510(k) Summary
for
SNORE-CURE Anti-snoring Appliance

1. **DATE PREPARED**

March 4, 1998

2. **SPONSOR INFORMATION**

Main Office

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c/o: Ortho-Tain, Inc.
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Mailing address

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Outside Regulatory Counsel

McDermott, Will & Emery
600 13th Street, N.W.
Washington, D.C. 20005-3096

(202) 756-8075 (telephone)
(202) 756-8087 (facsimile)

Contact Person: David L. Rosen, R.Ph., J.D.

3. DEVICE NAME

Proprietary Name: SNORE-CURE Anti-snoring Appliance

Common/Usual Name: Anti-snoring Appliance

Classification Name: Unclassified

4. DEVICE DESCRIPTION AND INTENDED USE

The SNORE-CURE Anti-snoring Appliance is intended as an aid in the alleviation of snoring by repositioning the lower jaw slightly forward and open together with the tongue to expand the patient's airway, thereby decreasing air turbulence.

5. PREDICATE DEVICE

The SNORE-CURE Anti-snoring Appliance is substantially equivalent to the Snore-Guard device by Distar Incorporated cleared by FDA on on April 14, 1989 under 510(k) K882303/C in design, materials, and intended use.

6. DEVICE TESTING

The SNORE-CURE Anti-snoring appliance is preformed and is substantially similar in design, materials and function to the Snore-Guard product by Distar Incorporated cleared by FDA on April 14, 1989 under 510(k) K882303/C. The SNORE-CURE, like the predicate device, the Snore-Guard, advances the mandible anteriorly and open the mandible vertically. The SNORE-CURE appliance advances the mandible 6-7mm anteriorly with an average overjet of 4mm and opens the mandible 8mm. The Snore-Guard advances the mandible about 6-8mm anteriorly, and opens the mandible 7-8mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ortho-Tain, Incorporated
C/O David L. Rosen, R.Ph., J.D.
Attorney at Law
McDermott, Will & Emery
600 13th Street N.W.
Washington, DC 20005-3096

Re: K980952
Trade Name: SNORE-CURE® Anti-Snoring Appliance
Regulatory Class: Unclassified
Product Code: LRK
Dated: March 12, 1998
Received: March 13, 1998

Dear Mr. Rosen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORIGINAL

510(k) Number (if known): Not assigned yet

Device Name: Trade Name: SNORE-CURE®
Anti-snoring Appliance

Indications for Use: The SNORE-CURE Anti-snoring Appliance is intended as an aid in the alleviation of snoring by repositioning the lower jaw slightly forward and open together with the tongue to expand the patient's airway, thereby decreasing air turbulence.

PLEASE DO NOT WRITE BELOW THIS LINE
(Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980952

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)