K073446

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:
Archtek, Inc.
12105 W. Cedar Dr.
Lakewood, CO 80228

FEE - 8

Date Summary Prepared: December 31, 2008

Contact Person:
Ian P. Gordon, Senior Vice President
Emergo Group, Inc.
1705 S. Capital of Texas Hwy., Suite 500
Austin, Texas, 78746
Telephone: 512.327.9997
Fax: 512-327-9998

Device Name:

Trade Name(s): Grind Guard

Classification Name: Mouthguard, Over-the-Counter
Panel: Dental
Product Code: OBR

Section 10 – Executive Summary

Device Description:

The Grind Guard is appliance is to be worn at night, covering the teeth of the upper arch, as a protection for those who suffer form the night time grinding of the teeth. It is composed of a soft, thermoformable material that is heated and briefly cooled and molded to fit user's upper teeth; shock-absorbing material cushions teeth on all sides during nocturnal bruxing.

Indications for Use:

Protection against bruxism or nighttime teeth grinding; to reduce damage to teeth, and to prevent the noise associated with bruxism or grinding.

Predicate Device Information:

This device is substantially equivalent to the Doctor's Night Guard, marketed by Dental Concepts under K053580.

Comparison to Predicate Device(s):

The Grind Guard is substantially equivalent with regard to indications for use, general technological characteristics, principle of operation, and material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Archtek, Incorporated
C/O Mr. Ian P. Gordon
Senior Vice President
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K073446
Trade/Device Name: Grind Guard
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: None
Product Code: OBR
Dated: December 6, 2007
Received: December 11, 2007

Dear Mr. Gordon:

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 (301) 443-6597 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

K073446

Indications for Use

510(k) Number (if known): _____

Device Name: Grind Guard

Indications for Use: Protection against bruxism or nighttime teeth grinding; to reduce damage to teeth, and to prevent the noise associated with bruxism or grinding.

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

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

510(k) Number: K073446