K090472

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

OCT 14 2009

Date Summary Prepared: October 6, 2009

Contact Person:
Krista Oakes
Emergo Group, Inc.
1705 S. Capital of Texas Hwy., Suite 500
Austin, Texas, 78746
Telephone: 512.327.9997
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Device Name:
Trade Name(s): Grind Guard
Classification Name: Mouthguard, Prescription
Panel: Dental
Product Code: MQC

Device Description:
The Grind Guard is appliance is to be worn at night, covering the teeth of the upper arch. 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. This device may not be used as an athletic mouth guard. This device should not be used by persons under the age of 18.

Indications for Use:

Prescription indications:
a. To protect against tooth damage bruxism and clenching caused by occlusal interferences,
b. Provide short term relief from muscle spasm due to occlusal interferences, and
c. Prevention of pain and chronic tension of temporomandibular joint syndrome components that are caused by chronic jaw clenching.

Predicate Device Information:
This device is substantially equivalent to the Archtek OTC Grind Guard cleared under K073446 and the SleepRight adjustable night guard, marketed as a prescription device by Splintek – Power Products Inc. under K071404.

Comparison to Predicate Device(s):

The Grind Guard is identical in design and material to the OTC device cleared under K073446. It is substantially equivalent with regard to prescription use and indications, general technological characteristics, principle of operation, and material to the prescription device cleared under K071404.

Testing and Conclusions:

An independent clinical study published by JADA supports the effectiveness of the Grind Guard for the relief of orofacial pain associated with temporomandibular disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Archtek, Incorporated
Ms. Krista Oakes
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K090472
Trade/Device Name: Grind Guard
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: September 4, 2009
Received: September 26, 2009

OCT 1 4 2009

Dear Ms. Oakes:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

K090472

1071

Indications for Use

510(k) Number (if known): _____

Device Name: Grind Guard

Indications for Use (Rx):

a. To protect against tooth damage bruxism and clenching caused by occlusal interferences,
b. Provide short term relief from muscle spasm due to occlusal interferences, and
c. Prevention of pain and chronic tension of temporomandibular joint syndrome components that are caused by chronic jaw clenching.

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

Kevin Mosley for MSR

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

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