510(k) Summary

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DATE PREPARED: October 18, 2011
TRADE OR PROPRIETARY NAME: BRUX MOUTHGUARDS
CLASSIFICATION NAME: MOUTHGUARDS
PREDICATE DEVICE: K073446

This summary includes only information that is also covered in the body of this 510(k) document, does not contain any puffery or unsubstantiated labeling claims, does not contain any raw data, i.e., contains only summary data, and does not contain any patient identification information. Confidential information is included.

DEVICE DESCRIPTION: BRUX MOUTHGUARDS are polymer trays that are used intraorally over the dentition. Two models are to be offered for upper (BRUX NIGHT), or lower (BRUX SPORT) dentition.

INTENDED USE: BRUX MOUTHGUARDS are indicated to help protect the teeth from damage caused by bruxism, sports injuries, and muscle contractions.

TECHNOLOGICAL CHARACTERISTICS vs. the predicate device: BRUX MOUTHGUARDS are essentially identical to the predicate device, Archtek Inc. Grind Guard (K073446).

Both BRUX MOUTHGUARDS (BRUX NIGHT and BRUX SPORT) and the predicate mouthguards are composed of EVA and designed for use over the dentition for protection from biting forces.

BRUX MOUTHGUARDS are available in limited colors.

OTHER: The BRUX MOUTHGUARD material was tested according to ISO 10991-1 guidelines for cytotoxicity (ISO 10993-5), oral irritation (ISO 10993-10) and skin sensitization (ISO 10993-10). The results of this testing show that the material of the BRUX MOUTHGUARDS was non-cytotoxic, and was neither an oral irritant, nor a skin sensitizer.

We believe that the performance data provided herein support the safety and effectiveness of use of BRUX MOUTHGUARDS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 8 2011

Dental Arte, Incorporated
C/O Ms. Carolyn M. Primus
Consultant
Primus Consulting
7046 Owl's Nest Terrace
Braderdon, Florida 34203

Re: K111310
Trade/Device Name: BRUX MOUTHGUARDS
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR, MQR
Dated: October 18, 2011
Received: October 28, 2011

Dear Ms. Primus:

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.

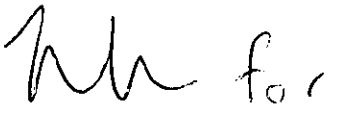
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/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,



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

Enclosure

Indications for Use

510(k) Number (if known):K111310

Device Name: BRUX MOUTHGUARDS

Indications For Use: BRUX MOUTHGUARDS are indicated to help protect the teeth from damage caused by bruxism, sports injuries, and muscle contractions.

Prescription Use ____ AND/OR Over-The-Counter Use _X_
(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) Susan Susan Runyon
Page 1 of 1

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

510(k) Number: K111310