Special 510(k) SUMMARY

DEC 19 2007

1. ***Submitter's Name:*** Dental Concepts, LLC
   Address: 90 North Broadway, Irvington, New York 10533
   Telephone Number: (914) 524-6842
   Contact Person: Karen A. Costa-Strachan, Ph.D.
   Date Prepared: November 14, 2007

2. ***Device Name:***
   Proprietary Name: The Doctor's® NightGuard™ Advanced Comfort™
   Common or Usual Name: Dental Protector (Over-the-Counter)
   Classification Name: Unclassified
   Product Code: OBR

3. ***Devices to Which Substantial Equivalence is Claimed:***

   Primary Predicate Device: Dental Concepts The Doctor's® NightGuard™ Classic™ (K053580)
   Secondary Predicate Device: Dental Concepts BruxGuard™ (K024261)

4. ***Device Description and Technological Characteristics:***
   The Doctor's® NightGuard™ Advanced Comfort™ is composed of a soft, formable clear upper material, made of ELVAX® resin (a copolymer of ethylene and vinyl acetate) and ELVALOY® (a copolymer of ethylene and methyl acrylate containing 9% methyl acrylate). When heated and then briefly cooled, the upper material can be molded to fit the user's upper teeth. The hard base prevents bite-through by users with moderate to severe nocturnal bruxing. The shock absorbing polymer material cushions the teeth on all sides.

5. ***Intended Use Statement:***
   The Doctor's® NightGuard™ Advanced Comfort™ is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

6. ***Performance Data:***
   No performance data is required in support of this Special 510(k) notice.

7. ***Substantial Equivalence:***
   The Doctor's® NightGuard™ Advanced Comfort™ possesses the same technological characteristics, principles of operation and intended use as the predicate devices (currently marketed The Doctor's® NightGuard™ Classic™ and BruxGuard™) . Therefore, The Doctor's® NightGuard™ Advanced Comfort™ is substantially equivalent to both predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2007

Karen Costa-Strachan, Ph.D.
Director Regulatory Affairs
Prestige Brands, Incorporated
90 N Broadway
Irvington, New York 10533

Re: K073220
Trade/Device Name: The Doctor's® NightGuard™ Advanced Comfort™
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: OBR
Dated: November 14, 2007
Received: November 23, 2007

Dear Dr. Costa-Strachan:

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

K073220

INDICATIONS FOR USE STATEMENT

Applicant: Dental Concepts, LLC

510(k) Number (if known): _____

Device Name: The Doctor's® NightGuard™ Advanced Comfort™

Indications for Use: The Doctor's® NightGuard™ Advanced Comfort™ is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

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

510(k) Number: K073220

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use X
(Per 21 CFR 801.109)