K060377

Tab 5

APR 2 6 2006

Premarket Notification [510(k)] Summary

Date Prepared: February 8, 2006

Trade Name: DR Disposable Prophy Angle

Common Name: Disposable Prophy Angle

Classification Name: Handpiece, Contra-and Right-Angle Attachment, Dental

Company Name: Dental Resources
Address: 400 Congress St. West
Maple Lake, MN 55358

Contact: Bryan Nichols
Title: Vice President of Operations
Telephone: 320.963.6267
Fax: 320.963.2029

Predicate Device: Oral-B Disposable Prophy Angle W/Prophy Cup, K932990.

Device Description: The DR Disposable Prophy Angle is a dental device that consists of a pair of gears, a turning spindle and a drive spindle enclosed in a plastic housing, that connects to a low speed dental handpiece. The turning spindle has a prophylaxis cup attached to the end which holds dental tooth polishing paste.

Intended Use: Professional dentists and dental hygienists use this type of device for polishing and cleaning the surface of teeth. The DR Disposable Prophy Angle is intended for single use, thus eliminating the possibility of cross contamination.

The DR Prophy Angle has the same intended use, performance and safety characteristics as the predicate device; see the following comparative table.

Technological Characteristics: Predicate Device Comparison Table

Device	Oral-B Disposable Prophy Angle with Prophy Cup 510(K) 932990	DR Disposable Prophy Angle
Usage	For **single use** by Dental Professionals to clean patient's teeth. Device is disposed of after use on one patient.	Same
Target Users	Professional Dentists and Hygienists	Same
Location of Use	Dental Offices	Same
Product Design	Plastic one-piece housing (external casing) with 1 internal drive shaft and a spindle installed and aligned at right angle (90 degree) with each other. Tip of spindle is fitted with the rubber prophy cup for cleaning and polishing teeth.	Same
Dimensions: Length Diameter	49mm 12mm at insert 9mm at end	49mm 12mm at insert 9mm at end
Sterility	Non-Sterile	Non-Sterile
Bio-compatibility	Prophy cups are made of natural rubber	Prophy cups are made of Non-Latex natural rubber.
Drive Mechanism	Rotation shafts driven by low speed dental hand piece	Same
Compatibility with dental hand piece	Designed to fit securely onto most ISO fitting standard slow speed dental hand pieces.	Same
Performance	Sufficient for one cleaning cycle for one patient.	Same
Mechanical Safety	Robust construction to withstand forces generated during cleaning cycle.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bryan Nichols
Vice President Operations
Dental Resources
400 Congress Street West
Maple Lake, Minnesota 55358

APR 26 2006

Re: K060377
Trade/Device Name: DR Disposable Prophy Angle
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: February 10, 2006
Received: February 15, 2006

Dear Mr. Nichols:

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

Tab 4

Statement of Indications For Use

510(k) Number (if known): K060377

Device Name: DR Disposable Prophy Angle

Indications for Use:

The DR Disposable Prophy Angle is a device intended to be attached to a low speed dental handpiece and used by professional dentists and dental hygienists for polishing and cleaning the surface of teeth. The DR Disposable Prophy Angle is intended for single use, thus eliminating the possibility of cross contamination.

Susan Runyon

[illegible]ony, General Hospital,
[illegible] Dental Devices

K060377

Prescription Use √ AND/OR Over-The-Counter Use_
(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)