K061252

FEB 1 2 2007

510(k) SUMMARY

Owner/Contact Information: Dr. Carolyn Primus 941-753-9737
Primus Consulting
7046 Owl's Nest Terrace
Bradenton, FL 34203

Date Summary Prepared: May 1, 2006

Draft Trade Name: Pre-Cemented Orthodontic Bracket System

FDA Classification Name and Number:
Bracket adhesive resin and tooth conditioner, 872.3750
Resin impression tray material, 872.3670

Legally Marketed Predicate Devices APC™ Plus Adhesive K020394

Description of the Device: The Pre-Cemented Orthodontic Bracket System consists of pre-cemented orthodontic brackets and an optional bonding tray. The orthodontic brackets and component used in the application are currently marketed medical devices.

Intended use: The Pre-Cemented Orthodontic Bracket System is indicated for use in bonding orthodontic appliances for orthodontic treatment.

Technological Characteristics: All of the components found in the Pre-Cemented Orthodontic Bracket System are legally marketed devices or are found in legally marketed devices. As there are no changes in formulation from the predicate devices, we believe that additional biocompatibility testing is not required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Carolyn M. Primus
Official Correspondent
Primus Consulting
7046 Owl's Nest Terrace
Bradenton, Florida 34203

FEB 12 2007

Re: K061252
Trade/Device Name: Pre-Cemented Orthodontic Bracket System
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: January 4, 2007
Received: January 22, 2007

Dear Dr. 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.

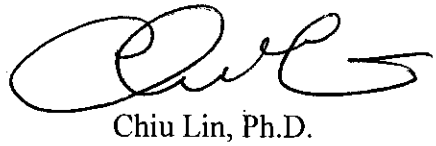
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(K) Number (if known): K061252

Device Name: Pre-Cemented Orthodontic Bracket System

Indications for Use:

Indicated for use in bonding orthodontic appliances for orthodontic treatment

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K061252