510(k) SUMMARY

K042178

AUG 3 0 2004

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT:	P. Jeffery Lehn
DATE PREPARED:	August 3, 2004
TRADE OR PROPRIETARY NAME:	ORTHODONTIC CERAMIC BRACKETS
CLASSIFICATION NAME:	Orthodontic Bracket, 872.5470
PREDICATE DEVICES:	Ceramic Orthodontic Bracket, K852179

DESCRIPTION OF DEVICE: The ORTHODONTIC CERAMIC BRACKETS are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontic wire, to alter the tooth position. The dimpled, beveled bracket base includes rhomboid and "torque-in-the-base" features. The modified ceramic, orthodontic brackets have indented walls and are available with or without glass coating in the wire slot. The modified brackets are more transparent than the predicate device.

INTENDED USE: Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

TECHNOLOGICAL CHARACTERISTICS: The function and performance of the modified brackets is very similar to the predicate. Minor design changes and a change in transparency are the only modifications made to K852179.

There are no changes in intended use or fundamental scientific technology. All of the materials in the device have been used in legally marketed DENTSPLY devices. We believe that the modified device is substantially equivalent to K852179.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2004

Dentsply International
C/O Mr. P Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K042178
Trade/Device Name: Orthodontic Ceramic Brackets
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: August 3, 2004
Received: August 11, 2004

Dear Mr. Lehn:

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.

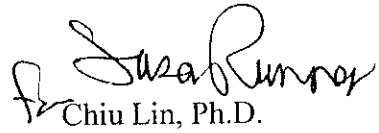
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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 STATEMENT

510(K) Number (if known): K042178

Device Name: ORTHODONTIC CERAMIC BRACKETS

Indications for Use:

Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

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

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDEI

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042178