K060937

510(k) SUMMARY

APR 10 2006

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: March 23, 2006

TRADE OR PROPRIETARY NAME: In-Ovation™ C

CLASSIFICATION NAME: Bracket, Ceramic, Orthodontic 21 CFR 872.5470

PREDICATE DEVICES: Orthodontic Ceramic Brackets (K042178)

DEVICE DESCRIPTION:

The In-Ovation™ C brackets are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontic wire, to alter the tooth position. The modified orthodontic ceramic bracket has both aesthetic and self-ligating qualities. The modifications were aimed at facilitating easier orthodontic wire placement and removal through self-ligation and enhancing the bonding and debonding characteristics of the bracket.

INTENDED USE:

The In-Ovation™ C is indicated for orthodontic movement of natural teeth, excluding the mandibular bicuspid teeth.

TECHNOLOGICAL CHARACTERISTICS:

The function and performance of the In-Ovation™ C bracket is similar to the predicate. Minor design changes and incorporation of self-ligation are the only modifications made to the Orthodontic Ceramic Brackets (Mystique®) (K042178).

There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed DENTSPLY devices. We believe that the modified device is substantially equivalent to the predicate Orthodontic Ceramic Brackets (Mystique®) (K042178).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2006

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K060837
Trade/Device Name: In-Ovation™ C
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: March 24, 2006
Received: March 28, 2006

Dear Ms. Lewis:

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" (21 CFR 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 S. Lin, PhD
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

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K060837

Device Name: In-Ovation™ C

Indications for Use:

In-Ovation™ C is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

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

Kevin Mulry for MSR

...ogy, General Hospital,

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