K123094

510(k) Summary

per 21CFR807.92

DEC 1 3 2012

CONTACT:

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DATE PREPARED: November 1, 2012

TRADE OR PROPRIETARY NAME: ORTHODONTIC CERAMIC BRACKETS

CLASSIFICATION NAME: Bracket, Ceramic, Orthodontic, 872.5470

PREDICATE DEVICES:

In-Ovation C ceramic brackets (K060837)
Mystique MB ceramic brackets (K082974)

DEVICE DESCRIPTION: The ORTHODONTIC CERAMIC BRACKETS are designed to move teeth to improve their alignment.

The ORTHODONTIC CERAMIC BRACKETS are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.

No accessories are marketed with the ORTHODONTIC CERAMIC BRACKETS. The dental clinician is free to choose the bonding cement, supplemental ligatures and orthodontic wires for use with the brackets.

INTENDED USES: The ORTHODONTIC CERAMIC BRACKETS are indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

TECHNOLOGICAL CHARACTERISTICS: The ORTHODONTIC CERAMIC BRACKETS are composed of a polycrystalline alumina ceramic bracket, which includes an archwire slot and tiewings. The self-ligating ORTHODONTIC CERAMIC BRACKETS have a metal clip so that no other ligation of the archwire is needed.

Bench testing was performed to ensure that the ORTHODONTIC CERAMIC BRACKETS' performance was achieved and validated, which consisted of friction tests, flexural strength measurements, translucency, and shear bond tests.

The ORTHODONTIC CERAMIC BRACKETS were not evaluated for biocompatibility because alumina has long been proven to be safe. All of the components have been used in legally marketed predicate orthodontic ceramic brackets. No new questions of safety and effectiveness are raised with these devices.

SUBSTANTIAL EQUIVALENCE: No differences exist between these ORTHODONTIC CERAMIC BRACKETS and the predicate devices currently marketed in intended use, composition, design, function, physical properties, or performance. We believe that the performance data provided herein demonstrate these ORTHODONTIC CERAMIC BRACKETS devices are substantially equivalent in safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

TOMY, Incorporated
C/O Carolyn M. Primus, PhD
Consultant
Primus Consulting
7046 Owl's Nest Terrace
BRADENTON FL 34203

Re: K123094
Trade/Device Name: Orthodontic Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: September 28, 2012
Received: October 25, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123094

Device Name: ORTHODONTIC CERAMIC BRACKETS

Indications For Use: Orthodontic Ceramic Brackets are 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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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