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K090454

DENTSPLY

DENTSPLY Internation
World Headquarters
Susquehanna Commerce C
221 West Philadelphia St
York, PA 17405-0872
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

510(k) SUMMARY
for
Allure® MB Ceramic Brackets

1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

Date Prepared: 19 February 2009

2. Device Name:
   - Proprietary Name: Allure® MB Ceramic Brackets
   - Classification Name: Bracket, Ceramic, Orthodontic
   - CFR Number: 872.5470
   - Device Class: II
   - Product Code: NJM

3. Sponsor's Predicate Device:

Company	Device	510(k) Number	Date Cleared
DENTSPLY International	Allure	K852179	08/20/1985
DENTSPLY International	Mystique MB Ceramic Brackets	K082974	11/07/2008

4. Description of Device:

The marketed product Allure® has a chemically treated base. A modification has been made to replace that base with a new mechanical lock base, Allure® MB. The mechanical lock base includes rhomboid and "torque-in-the-base" features.

5. Indications for Use:

Allure® MB Ceramic Brackets and Mystique MB Ceramic Brackets are indicated for orthodontic movement of natural teeth excluding mandibular bicuspid teeth.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

The Allure® MB Ceramic Brackets represent a modification to K852179.

All of the components found in Allure® MB Ceramic Brackets have been used in legally marketed devices and/or were found safe for dental use. Allure® MB Ceramic Brackets are the same composition as the predicate devices. Therefore, further biocompatibility testing is not necessary.

We believe that the prior use of the component of Allure® MB Ceramic Brackets in legally marketed devices, the performance data provided, and the previously submitted biocompatibility data provide support regarding the safety and effectiveness of Allure® MB Ceramic Brackets for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2009

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

Re: K090454
Trade/Device Name: Allure® MB Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: February 19, 2009
Received: February 23, 2009

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.

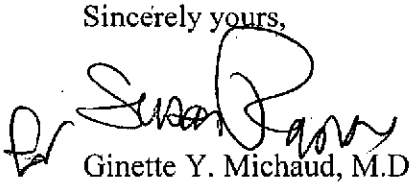
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting 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): K090454

Device Name: Allure® MB Ceramic Brackets

Indications for Use:

Allure® MB ceramic brackets are indicated for the 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 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K090454