K090933

JUN - 5 2009

510(k) Summary of Safety & Effectiveness

in accordance with requirements 21 CFR 807.92.

1. Company

Bernhard Forster GmbH
Westliche Karl- Friedrichstraße 151
75172 Pforzheim - Germany

Telephone: 049-7231-459-0
Fax: 049-7231-459-102
Contact: Michael Fieß

2. Device

Proprietary - trade name : Orthodontic Ceramic Brackets
Classification name: Bracket, Ceramic, Orthodontic, product code NJM

3. Equivalent legally marketed devices:

Orthodontic Ceramic Bracket Innovation C (K060837), Dentsply International

4. Indication for use:

The device is intended for orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single used only.

5. Description of the device

The Orthodontic Ceramic Brackets are bonded to teeth to apply forces to the tooth, transmitted through a flexible orthodontic wire , to alter the tooth position. The ceramic bracket has both, aesthetic and self ligating qualities. This aimed at facilitating easier orthodontic wire placement and removal through self- ligatation

The function and performance of the orthodontic ceramic brackets are equal to the predicate device.

The Material was selected according the requirements of ISO 6474:1994. Ceramic materials based on High purity aluminia.

Device name	In- Ovation C Dentsply	Bernhard Forster GmbH Orthodontic Ceramic brackets
Device classification name	Orthodontic Ceramic Bracket CFR 872.5470, NJM	Orthodontic Ceramic bracket CFR 872.5470; NJM
Applicant	Dentsply International	Bernhard Forster GmbH
510(k) - Number	(K060837)	This submission
Material	Al2O3	ALSO3
Intended use	The innovation C is intended for orthodontic movement of natural teeth , excluding the mandibular bicuspid teeth .	The device is intended for orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single used only.
Single use?	YES	YES
Sterility	Non-sterile	Non-sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

Mr. Michael Fieb
Regulatory Affairs Manager
Forestadent Bernhard Förster GmbH
Westliche Karl- Friedrich-Straße 151
75172 Pforzheim GERMANY

Re: K090933
Trade/Device Name: Orthodontic Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: March 31, 2009
Received: April 2, 2009

Dear Mr. Fieb:

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 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/cdrh/comp/ 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090933

4. Indications for Use

510(k) Number (if known):

Device Name: Orthodontic Ceramic Brackets

Indications For Use: The device is intended for orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single used only.

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)

Lori Mulvey for MSR

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

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