K101481

BioMers

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JUN 23 2010

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

BioMers Products LLC.
18912 North Creek Parkway, Suite 210
Bothell, WA, 98011,

Contact Person: George Aliphtiras, Vice President of Business Development
Tel: 425-487-3000
Fax: 425-487-3813
Email: george@biomersbraces.com

Date Prepared: March 15, 2010

II. Device Name

Proprietary Name:	BioMers Translucent Orthodontic Bracket
Common/ Usual Name:	Orthodontic Plastic Bracket
Classification Name:	Orthodontic appliance and accessories
Regulation Number:	872.5470
Product Codes:	NJM
Classification:	II
Classification Panel:	Dental

III. Predicate Device

The BioMers Translucent Orthodontic Bracket is substantially equivalent to the Absolute bracket from Star Dentech Korea, Corp. and the PURE Sapphire bracket from Ortho Technology. The Absolute bracket was most recently cleared by the FDA on May 27, 2009 under 510(k) K090567. The PURE Sapphire bracket was cleared by the FDA on December 18, 2007 under 510(k) K073045.

IV. Intended Use of the Device

The Translucent Orthodontic Bracket is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

V. Description of the Device

The Translucent Orthodontic Bracket is comprised of single crystal alumina. The translucent properties of the bracket make the bracket less visible than polycrystalline ceramic and metal brackets. The bracket consists of three distinct parts: (1) arch wire slot, (2) four tie wings, and (3) base. The arch wire slot allows the placement of an arch wire which applies the necessary

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force to effect tooth movement. The tie wings allow the placement of an elastic o-ring, which holds the arch wire in place. The base is adhered to a patient's tooth using adhesive, thereby anchoring the bracket to the tooth.

VI. Summary of the Technical Characteristics

The BioMers Orthodontic Bracket was designed and tested using ISO 11405:2003 - Dental materials -- Testing of adhesion to tooth structure

The BioMers Translucent Orthodontic Bracket has similar technological characteristics as the predicate devices: Absolute bracket (Star Dentech Korea, Corp.) and PURE Sapphire bracket (Ortho Technology).

	BioMers Products	**Star Dentech Korea**	**Ortho Technology**
Product Name	BioMers Translucent Orthodontic Bracket	Absolute	PURE Sapphire
510(k) Number	Not assigned	K090567	K073045
Product Code(s)	NJM	NJM	NJM
Regulation #	872.5470	872.5470	872.5470
Class	II	II	II
Intended Use	Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.	Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.	Indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.
Material Composition	Al_2O_3 (single crystal alumina)	Al_2O_3 (single crystal alumina)	Al_2O_3 (single crystal alumina)
Translucent	Yes	Yes	Yes
Standards	ISO 11405:2003 - Dental materials -- Testing of adhesion to tooth structure	Not known	Not known
Bracket Design	Twin bracket	Twin bracket	Twin bracket
Biocompatibility	Meets the applicable requirements of ISO 10993	Meets the applicable requirements of ISO 10993	Meets the applicable requirements of ISO 10993
Available Slot Sizes	0.018", 0.022"	0.018", 0.022"	0.018", 0.022"
Available Prescriptions	Standard-Edgewise, Roth & High Torque	Roth & High Torque	Standard-Edgewise, Roth& High Torque
Bond Strength* (MPa)	11.73 ± 3.04	5.51 ± 1.65	19.41 ± 5.08

**Bond strength testing was carried out according to ISO 11405-2003(E).*

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VII. Safety & Effectiveness

The Translucent Orthodontic Bracket has the same intended use and similar technological characteristics as the predicate devices. The differences in technological characteristics between the new device and the predicate device do not raise issues of safety and effectiveness of the Translucent Orthodontic Bracket. Bench tests and functional testing studies, according to ISO 11405:2003 - Dental materials -- Testing of adhesion to tooth structure were conducted. The risk analysis was conducted according to ISO 14971:2007. Applicable biocompatibility testing was in accordance to the requirements of ISO 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BioMers Products, LLC
C/O Ms. Paula Wilkerson
Intertek Testing, Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

JUN 2 3 2010

Re: K101481
Trade/Device Name: BioMers Translucent Orthodontic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: June 11, 2010
Received: June 14, 2010

Dear Ms. Wilkerson:

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,

Susan Runner

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

Enclosure

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4. Indication for Use Statement

510(k) Number (if known):

Device Name: BioMers Translucent Orthodontic Bracket

Indications for Use:

- The Translucent Orthodontic Bracket is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

Ken Mulky for MSR

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

510(k) Number: K101481

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)