K110796

BioMers

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MAR 3 1 2011

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

BioMers Products, LLC
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Bothell, WA 98011, USA

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Date Prepared: 6 January 2011

II. Device Name

Proprietary Name:	SimpliClear Rectangular Orthodontic Wire
Common/ Usual Name:	Orthodontic wire
Classification Name:	Orthodontic plastic bracket
Regulation Number:	872.5470
Product Codes:	DYW, DZC
Classification:	II
Classification Panel:	Dental

III. Intended Use of the Device

The SimpliClear Rectangular Orthodontic Wire is indicated for use as an orthodontic archwire to provide force to the teeth to effect movement in orthodontic treatment.

IV. Description of the Device

The SimpliClear Rectangular Orthodontic Wire is a translucent archwire comprised of glass fibers, a polymer composite resin, and a polymer coating. The embedded glass fibers function as the reinforcement, providing the necessary force to straighten teeth. The translucent polymer composite resin serves as the matrix, binding together the individual glass fibers. The outer coating, made of a USP Class VI polycrystalline and amorphous linear polymer, increases the abrasion resistance properties of the wire.

V. Comparison to Predicate Device(s)

The SimpliClear Rectangular Orthodontic Wire is substantially equivalent in terms of composition to the BioMers Translucent Orthodontic Wire, and substantially equivalent in terms of mechanical properties to the Ormco Nickel Titanium, beta-Titanium and stainless steel rectangular wires. The

BioMers Translucent Orthodontic Wire was cleared by the FDA on May 2, 2008 under 510(k) K081143. The Ormco wires are exempt from 510(k) filings.

	BioMers Products LLC	BioMers Products LLC	Ormco Corp.
Product Name	**SimpliClear Rectangular Orthodontic Wire**	**BioMers Translucent Orthodontic Wire**	**Nickel Titanium (NiTi), beta-Titanium (beta-Ti) and Stainless Steel (SS) Rectangular Orthodontic Wire**
510(k) Number	Not assigned	K081143	Exempt
Intended Use	An orthodontic archwire used to provide force to the teeth to effect movement in orthodontic treatment.	An orthodontic arch wire used to provide force to the teeth to effect movement in the early (leveling and aligning) stage of orthodontic treatment.	Orthodontic arch wire
Material Composition	Glass fibers with a polymer composite resin, and a polymer coating *(same as K081143)*	Glass fibers with a polymer composite resin, and a polymer coating	Nickel Titanium, beta-Titanium and Stainless Steel
Biocompatibility	Meets the applicable requirements of ISO10993	Meets the applicable requirements of ISO10993	Meets the applicable requirements of ISO10993
Performance Testing			
Elastic Modulus *A measurement of an object or substance's tendency to be deformed elastically (i.e., non-permanently) when a force is applied to it. The elastic modulus of an object is defined as the slope of its stress-strain curve in the elastic deformation region. Tested per ASTM D3916-02.*	At similar wire dimensions, the elastic modulus of the SimpliClear Rectangular Orthodontic Wire is greater than the range established by the Ormco Rectangular Orthodontic Wire made of NiTi and beta-Ti and that of the BioMers Translucent Orthodontic Wire. However, as the Elastic Modulus refers to a material's ability to undergo elastic deformation, in other words the ability of the archwire to deform under an applied load and recover to its original state when the load is removed, the higher values from the SimpliClear Rectangular Orthodontic Wire do not raise safety or effectiveness issues as compared to the predicate devices.		
Tensile Strength *The maximum stress that a material can withstand while being stretched or pulled. Tested per ASTM D3916-02.*	At similar wire dimensions, the tensile strength of the SimpliClear Rectangular Orthodontic Wire is within the range established by the Ormco Rectangular Orthodontic Wire made of NiTi and beta-Ti and that of the BioMers Translucent Orthodontic Wire.		
Flexural Strength *Defined as a material's ability to resist deformation under load. Tested per ASTM D790-03.*	At similar wire dimensions, the flexural strength of the SimpliClear Rectangular Orthodontic Wire is within the range established by the Ormco Rectangular Orthodontic Wire made of NiTi and beta-Ti.		

	BioMers Products LLC	BioMers Products LLC	Ormco Corp.
Product Name	**SimpliClear Rectangular Orthodontic Wire**	**BioMers Translucent Orthodontic Wire**	**Nickel Titanium (NiTi), beta-Titanium (beta-Ti) and Stainless Steel (SS) Rectangular Orthodontic Wire**
Flexural Modulus *The ratio of stress to strain in flexural deformation, or the tendency for a material to bend. Tested per ASTM D790-03*	At similar wire dimensions, the flexural modulus of the SimpliClear Rectangular Orthodontic Wire is within the range established by the Ormco Rectangular Orthodontic Wire made of NiTi and beta-Ti.		

VI. Conclusion

There are no known substantial differences in terms of composition and mechanical properties between the SimpliClear Rectangular Orthodontic Wire defined in this 510(k) submission and the BioMers Translucent Orthodontic Wire, and the Ormco Rectangular Wire composed of Nickel Titanium, beta-Titanium, and stainless steel, respectively. The intended uses are comparable and any differences in technological characteristics do not raise issues of safety and effectiveness. Therefore, the SimpliClear Rectangular Orthodontic Wire is substantially equivalent to BioMers Translucent Orthodontic Wire and the Ormco Rectangular Wire.

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 Mr. William Sammons
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

MAR 31 2011

Re: K110796
Trade/Device Name: SimpliClear Rectangular Orthodontic Wire
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW, DZC
Dated: March 16, 2011
Received: March 22, 2011

Dear Mr. Sammons:

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,

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

BioMers

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4. Indication for Use Statement

510(k) Number (if known): K110796

Device Name: SimpliClear Rectangular Orthodontic Wire

Indications for Use:

An orthodontic archwire used to provide force to the teeth to effect movement in orthodontic treatment.

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)

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

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