K141104

JUN 25 2014

510(k) SUMMARY
(as required by 807.92(c))

Regulatory Correspondent:

AJW Technology Consultants Inc.
445 Apollo Beach Blvd
Apollo Beach, FL 33572
Contact: Tanya O'Brien
tmobrien@ajwtech.com
813-645-2855 x102
813-645-2856

Submitter of 510(k):

Bernhard Forster GmbH
Westliche Karl – Friedrichstraße 151
75172 Pforzheim, Germany
Contact: Michael Fiess
michael.fiess@forestadent.com
Telephone: 049-7231-459-0
Fax: 049-7231-459-102

Date of Summary: June 17, 2014

Trade/Proprietary Name: TruKlear Orthodontic Ceramic Brackets

Common Name: Bracket, Ceramic, Orthodontic

Classification Name: Orthodontic Ceramic Bracket

Device Class: II

Regulation Number: 872.5470

Device Panel: Dental

Product Code: NJM

Intended Use:

This 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 for single use only.

Device Description:

The Orthodontic Ceramic Brackets are bonded to teeth to apply forces to the tooth, transmitted, to alter the tooth position. The force is introduced by a flexible orthodontic wire, which is attached to Orthodontic Ceramic Brackets. The ceramic bracket has both, aesthetic and self ligating qualities. The bracket design enables easier orthodontic wire placement and removal through self-ligating properties.

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 are based on High purity aluminia.

Substantial Equivalence:

The Orthodontic Ceramic Brackets are substantial equivalent in intended use and similar technological characteristics to the:

Orthodontic Ceramic Brackets (K090933) for the orthodontic movement of teeth to alter tooth position.

Applicant and Device Name	Forestadent Bernhard Forster GmbH Orthodontic Ceramic brackets TruKlear	Forestadent Bernhard Forster GmbH Orthodontic Ceramic brackets QuicKlear
510(k) - Number	This submission	(K090933)
Device classification name	Orthodontic Ceramic Bracket CFR 872.5470, NJM	Orthodontic Ceramic bracket CFR 872.5470; NJM
Material	AL2O3 mechanism plastic material	AL2O3
Intended 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.	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	Single Use	Single Use
Sterility	Non-sterile	Non-sterile
Method of tooth adhesion	Bonding to tooth	Bonding to tooth

Method of tooth movement	Application of force through orthodontic wire	Application of force through orthodontic wire
Performance	Self-ligating , aesthetic ceramic bracket	Self-ligating , aesthetic ceramic bracket
Slide mechanism	Ceramic slide mechanism	Metallic clip

Rational for Substantial Equivalence:

The testing completed in the previously cleared submissions along with the additional testing completed demonstrates that the new TruKlear bracket exhibits comparable mechanical and functional characteristics to the predicate devices in addition to being biocompatible acceptable. Based on those characteristics, the Forestadent Bernhard-Forster TruKlear bracket is substantially equivalent to the predicate devices in safety and effectiveness in addition to being intended for the same uses.

Summary of Non-Clinical Data:

The TruKlear bracket underwent bench testing according to several different performance standards. Below is a chart of the different testing that was completed.

Device	Performance Test	Standard of Compliance
TruKlear Bracket	Material Strength	Din EN ISO 27020
	Slider Mechanism	Din EN ISO 27020
	Bonding Test	DIN 13990-2

Summary of Biocompatibility Testing:

The TruKlear bracket underwent biocompatibility testing according to several different performance standards. Below is a list of the different testing that was completed:

1. Acute Systemic Toxicity in Mouse according to ISO 10993-1: 2009, ISO 10993-11: 2006, ISO 10993-12:2012.
2. Cytotoxicity Growth Inhibition Test according to ISO 10993-5, ISO 10993-12.
3. Extractable Organic Substances after Liquid Extraction according to ISO 10993-18 and ISO 10993-12.
4. Irritation Test according to ISO 10993-1: 2009, ISO 10993-10: 2010, and ISO 10993-12: 2012.
5. Reverse Mutation Assay according to ISO 10993-1: 2009, ISO 10993-3: 2003, and ISO 10993-12: 2012.
6. Delayed Type Hypersensitivity Nonpolar Extract according to ISO 10993-1: 2009, ISO 10993-10: 2010, and ISO 10993-12: 2012.
7. Delayed Type Hypersensitivity Polar Extract according to ISO 10993-1: 2009, ISO 10993-10: 2010 and ISO 10993-12: 2012.

Conclusion

Based on the conclusions of each of these tests it is determined that the TruKlear bracket demonstrates that the device is substantially equivalent 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 20993-0002

June 25, 2014

Bernhard Forster GmbH
c/o Ms. Tanya O'Brien RN/BSN/CPAN
AWJ Technology Consultants, Inc.
445 Apollo Beach Boulevard
Apollo Beach, FL 33572

Re: K141104
Trade/Device Name: TruKlear Orthodontic Ceramic Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Bracket, Ceramic, Orthodontic
Regulatory Class: II
Product Code: NJM
Dated: May 21, 2014
Received: May 27, 2014

Dear Ms. O'Brien:

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 contact 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
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): K141104

Device Name: Orthodontic Ceramic Bracket

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 for single use 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Sheena A. Green -S
2014.06.23 09:49:25 -04'00'