DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 27, 2016

World Bio Tech Co., Ltd
% Mr. Peter Chung
Plus Global
300, Atwood
Pittsburgh, Pennsylvania 15213

Re: K152167
Trade/Device Name: BIJOU Orthodontic Ceramic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: April 8, 2016
Received: April 19, 2016

Dear Mr. Chung:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No.0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k} Number *(if known)*

K152167

Device Name
BIJOU Orthodontic Ceramic Bracket

Indications for Use *(Describe)*
BIJOU Orthodontic Ceramic bracket is indicated for orthodontic movement of natural teeth.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH} *(Signature)*

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510(k) Summary K152167

Submitter's Name: WORLD BIO TECH CO., LTD.
Submitter's Address: #302 BizCenter, SknTechnoPark, 124, Sagimakgol-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

Submitter's Telephone: +82-31-776-2804
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Submitter's Contact: Jin-kyu Park

Date 510(k) summary prepared: April 8, 2016

Proprietary Name: BIJOU Orthodontic Ceramic Bracket

Common or Usual Name: Orthodontic Ceramic Bracket

Classification Name: Orthodontic plastic bracket

Regulation Number: 21 CFR 872.5470

Review Panel: Dental

Product Code: NJM

Classification Code: II

Type of 510(k) submission: Traditional

Predicate Device: K073045 / PURE Sapphire / Ortho Technology, Inc.

Description of the Device

Orthodontic Ceramic bracket, BIJOU is composed of single crystal alumina and consists of three parts: the first part is the slot for the orthodontic wire; the second part is a round groove that is to hold a wire with an elastic "O" ring; the third part is the base that adheres to the tooth surface. A colored marking on wing part of bracket indicates orientation for placement.

Indications for Use

BIJOU Orthodontic Ceramic bracket are indicated for orthodontic movement of natural teeth.

PURE Sapphire, (K073045), and BIJOU have similar technological characteristics:

Substantial Equivalence

Table 1: Substantial equivalence comparison

Manufacturer	**WORLD BIO TECH CO., LTD.**	**Ortho Technology, Inc.**
510(k) Number	K152167	K073045
Common/Generic Name	Orthodontic Ceramic Bracket	Sapphire Ceramic Bracket
Trade/Proprietary Name	BIJOU	PURE®
Intended use	BIJOU Orthodontic Ceramic bracket are indicated for orthodontic movement of natural teeth.	Sapphire Ceramic Brackets are indicated for the orthodontic movement of teeth.The devices are for Orthodontic Use Only, on the order of an Orthodontist.
Material composition of Bracket	**Al_2O_3 (single crystal alumina)**	**Al_2O_3 (single crystal alumina)**
Material composition of colorants for bracket placement orientation	Yellow (C.I. Food Yellow 4), Blue (C. I. Acid Blue 9, disodium salt), Red (FD&C Red No.3), and Pink (Carmine B.C.)	Not known
Translucent	**Yes**	**Yes**
Bracket design	Standard, Roth, MBT designs with and without hook, conforming to ISO 27020:2010 Dentistry – Brackets and tube for Use in Orthodontics	Standard, Roth, MBT designs with and without hook
Bracket In-out(mm)	1.03 – 1.44	0.53 – 0.89
Bracket Torque(º)	-7 to +17	- 7 to +17
Available slot sizes	0.018 / 0.022 inch	0.018 / 0.022 inch
Orientation marking	Colored dot on external surface	Colored dot on external surface
Single use	**Yes**	**Yes**
Non-Sterile packaging	**Yes**	**Yes**

The indication for use on natural teeth stated in the submission indications for use statement, as well as the omission of the statement for orthodontic use only and on order of an orthodontist, do not change the intended use of the device as both the submission device and

the predicate device are prescription devices for use in orthodontic treatment. The available bracket designs are similar; the slight variation in design of the maxillary in-out ranges is within the acceptable range for ISO 27020. The material used for the preformed translucent block form shapes. While both the submission device and the predicate device are marked with a colorant for orientation during placement and the colorants for the submission device may be different from the predicate device, the submission includes biocompatibility testing. The overall design is identical as a translucent, twin bracket with identical wire slot size;.

Biocompatibility

Biocompatibility testing including cytotoxicity, sensitization, oral mucosal irritation was completed according to the following standards:

ISO 10993-1 Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity

ISO 10993-10 Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization

ISO 10993-12 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

Non-clinical Performance Data

Non-clinical performance testing was conducted as follows: design characteristics based on and in accordance with ISO 27020:2010 Dentistry – Brackets and tubes for use in Orthodontics; adhesive strength and analysis of detached teeth surface were conducted in accordance with ISO 11405:2015, Dentistry –Testing of adhesion to tooth structure; in-house comparative performance testing was conducted for the submission device and the predicate device, including wire slot drag test, wire slot torque test, shear test, and bracket removal test. A risk analysis was conducted based on ISO 14971:2012 Medical devices – Application of risk management to medical devices

Clinical Data

No clinical performance testing was performed on BIJOU, ceramic brackets.

Conclusion

Based upon the chemical composition, design, indications for use, and results of non-clinical performance testing, we conclude that our device BIJOU is substantially equivalent to the predicate device.