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

Biocetec Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

June 14, 2017

Re: K163467
Trade/Device Name: C-Line Orthodontic Ceramic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: May 17, 2017
Received: May 22, 2017

Dear Dave Kim:

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,

Mary S. Runner -A

Tina Kiang, Ph.D.
Acting 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)*

Device Name
C-LineTM Orthodontic Ceramic Bracket

Indications for Use *(Describe)*

C-LineTM orthodontic ceramic bracket is intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: May 17, 2017

I. SUBMITTER

Submitter's Name	BIOCETEC CO., LTD.
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II. DEVICE

Trade/proprietary Name	C-Line™ Orthodontic Ceramic Bracket
Common or Usual Name	Orthodontic Ceramic Bracket
Regulation Name	Bracket, Ceramic, Orthodontic
Regulation Number	21 CFR 872.5470
Product Code	NJM
Regulatory Class	Class II

III. PREDICATE DEVICE

Primary Manufacturer	3M UNITEK Corporation
Device Name	Clarity Advanced Ceramic Bracket
510(k) Number	K102803
Regulation Name	Orthodontic Plastic Bracket
Regulation Number	21 CFR 872.5470 (Product Code: NJM)
Regulatory Class	Class II
Over the Counter Use	

IV. REFERENCE DEVICE

Trade/proprietary Name	Transbond™ XT

510(k) Number	K073697
Regulation Name	Adhesive, bracket and tooth conditioner, resin
Regulation Number	21 CFR 872.3750
Product Code	DYH
Regulatory Class	Class II

V. DEVICE DESCRIPTION

C-Line ™ orthodontic ceramic brackets are intended to be bonded to a tooth to apply pressure to a tooth to alter its position. C-Line ™ orthodontic ceramic brackets consist of a translucent alumina body and a bonding base. The bracket's color marking and cords indicates the bracket positioning and facilitate bracket identification.

VI. INDICATIONS FOR USE:

C-Line™ orthodontic ceramic bracket is intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.

VII. PREDICATE COMPARISON

	Candidate Device	**Predicate 1**	**Substantial Equivalence Analysis**
510(k) Number	Pending	K102803	-
Device Name	C-Line™	Clarity™ Advanced Ceramic Brackets	-
Common Name	Orthodontic Ceramic bracket	Orthodontic Ceramic bracket	-
Manufacturer	BIO CETEC CORPORATION	3M Unitek Corp.	-
Indication for Use	C-Line™ orthodontic ceramic bracket is intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.	Clarity™ Advanced Ceramic Brackets are intended for use in orthodontic treatment. The brackets are affixed to teeth so that pressure can be exerted on the teeth.	Substantial Equivalence
Material composition of Bracket	Polycrystalline Alumina(100%)	Polycrystalline Alumina(100%)	Substantial Equivalence
Material composition of colorants for	Polyvinylpyrrolidone(25wt%) Sweet whey powder(25wt%)	-	Different

bracket placement orientation	TiO2(25wt%) Food dye(25wt%)		
Transparency	Half-transparency	Half-transparency	Substantial Equivalence
Bracket design	MBT, ROTH designs with and without hook, conforming to ISO 27020:2010 Dentistry – Brackets and tube for Use in Orthodontics	MBT, ROTH, High Torque designs with and without hook, conforming to ISO 27020:2010 Dentistry – Brackets and tube for Use in Orthodontics	Substantial Equivalence
Design parts	Hook, Slot, Round home, base and marking	Hook, Slot, Round home, base and marking	Substantial Equivalence
Bracket In-out(mm)	0.56 to 1.45	0.51 to 1.14	Different
Bracket Torque(°)	-22 to +17	-17 to +17	Different
Bracket Angulation(°)	0 to 11	0 to 11	Substantial Equivalence
Available slot sizes	0.018 / 0.022 inch	0.018 / 0.022 inch	Substantial Equivalence
Orientation marking	Yes	Yes	Substantial Equivalence
Sing use	Yes	Yes	Substantial Equivalence
Non-Sterile Packaging	Yes	Yes	Substantial Equivalence
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Substantial Equivalence
Anatomical Site	Teeth	Teeth	Substantial Equivalence
Location of Use	Use only by professional orthodontists	Use only by professional orthodontists	Substantial Equivalence
Bio-compatibility	All user directly contacting materials are compliance with ISO10993 requirements.	All user directly contacting materials are compliance with ISO10993 requirements.	Substantial Equivalence

C-Line™ and the predicate device have identical indication for use statements and the same intended use.

The 510k(k) also includes data from bench testing to evaluate the performance of C-Line™ to the predicate device. The properties evaluated include wire slot drag test, wire slot torque test, shear test, and bracket removal test.

There are differences in the device design characteristics. The subject device's bracket in-out is 0.56 to 1.45 mm whereas the predicate device's range is between 0.51 to 1.14 mm. The bracket torque for the subject device is -22 to +17° wider than the predicate device's-17 to +17°. Also, the predicate device and subject device have a different color coding system to indicate the bracket positioning and identification.

These differences do not raise different questions of safety or effectiveness.

VIII. SUMMARY OF NON-CLINICAL TESTS

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:

According to the bench test result of the two ceramic brackets, their performances in the technical property seemed similar to one another. In the Wire Slot Torque test, C-Line brackets had higher torque strength than Clarity Advanced brackets due to the higher in/out thickness of C-Line.
In the Shear Bonding test, two brackets had a very similar shear strength. When two ceramic brackets were debonded, there were no fracture occurred.
The removal test with plier showed that the most of adhesive remained on the enamel despite of base patterns. C-Line brackets had a tendency to remain adhesive lower than Clarity Advanced because of undercut pattern base.
In the Wire Drag Test, the result of test data was similar for both brackets. Because two brackets were made of same raw materials(Alumina) and the structure of both product is poly-crystal alumina. Also, the width of the slot is approximatively the same as each other.

IX. BIOCOMPATIBILTY TESTING

Biocompatibility testing including cytotoxicity, sensitization, oral mucosal irritation was completed according to the following standards:
ISO 10993-1 (2010) Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ISO 10993-5 (2009) Biological Evaluation of Medical Devices – Part 5 Cytotoxicity
ISO 10993-10 (2010) Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization
ISO 10993-11 (2006) Biological Evaluation of Medical Devices Part 11: Tests for systemic toxicity test
ISO 10993-14 (2001) Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics

X. SUMMARY OF CLINICAL TESTS

Clinical testing was not required to demonstrate the substantial equivalence of the C-Line™ orthodontic ceramic bracket to its predicate device.

XI. CONCLUSIONS

Based on the information above, C-Line™ orthodontic ceramic bracket have similar indications for use and intended use. Both have shown similar performance results in these bench tests In conclusion, C-Line™ orthodontic ceramic bracket is substantially equivalent to the predicate device and would be comparable with Clarity Advanced ceramic bracket in functional performance during the course of orthodontic treatment.