Bio Cetec Co., Ltd.
% Dave Kim, MBA
President
MTech Group
8310 Buffalo Speedway
Houston, Texas 77025

January 22, 2019

Re: K182193
Trade/Device Name: S-Line™
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: October 17, 2018
Received: October 26, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.22 15:35:16 -05'00'

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182193

Device Name
S-Line™

Indications for Use *(Describe)*

S-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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date: January 22, 2019

1. 510K Applicant / Submitter:

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Fax: +82-2-704-2877

2. Submission Contact Person

MTech Group.
8310 Buffalo Speedway, Houston, TX 77025
Mr. Dave Kim, MBA
Phone: 713-467-2607 Fax: 713-583-8988
Email: davekim@mtech-inc.net

3. Device

Trade / Device Name:	S-Line ™
Classification Name:	Bracket, Ceramic, Orthodontic
Regulation Number:	21CFR 872.5470
Regulation Name:	Orthodontic Plastic Bracket
Regulatory Class:	II
Product Code:	NJM

4. Predicate Device :

Trade / Device Name:	C-Line™ Orthodontic Ceramic Bracket
510(k) Number	K163467
Regulation Number:	21 CFR 872.5470
Regulation Name:	Orthodontic Plastic Bracket
Regulatory Class:	II
Product Code:	NJM

5. Reference Device 1:

Trade / Device Name:	DAMON 4Clear by Ormco Corporation
510(k) Number:	K081415
Regulation Number:	21 CFR 872.5470
Regulation Name:	Orthodontic Plastic Bracket

Regulatory Class: II
Product Code: NJM

Reference Device 2:

Trade/proprietary Name	Transbond™ XT
510(k) Number	K073697
Regulation Name	Adhesive, bracket and tooth conditioner, resin
Regulation Number	21 CFR 872.3750
Regulatory Class:	Class II
Product Code	DYH

6. Description:

S-Line™ orthodontic ceramic bracket is used to treat malocclusion, the abnormal occlusion of the upper and the lower teeth. It is intended to be applied on the surface of teeth to restore dental esthetics and functionality and it is designed to be used jointly with orthodontic wire.

7. Indications for Use

S-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.

8. Substantial Equivalence Discussion:

[S-Line™ vs. C-Line™(K163467)]

S-Line™ Orthodontic Ceramic bracket is substantially equivalent to C-Line™(K163467). C-Line™(K163467) is also manufactured by BIO CETEC Corporation. The differences of two products include ligating method & bracket structure. The following comparison table is presented to demonstrate substantial equivalence.

	Subject Device	**Predicate 1**	**Substantial Equivalence Analysis**
510(k) Number	K182193	K163467	-
Device Name	S-Line™	C-Line™	-
Common Name	Orthodontic Plastic bracket	Orthodontic Ceramic bracket	-
Manufacturer	BIO CETEC CORPORATION	BIO CETEC CORPORATION	-
Indication for Use	S-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	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.	Substantial Equivalence
Material composition of Bracket	Polycrystalline Alumina(100%)	Polycrystalline Alumina(100%)	Substantial Equivalence

Material composition of Door	Polycrystalline Alumina(100%)	N/A	Different--
Material composition of snap ring & pin	300 Series Stainless Steel	N/A	Different-
Material composition of colorants for bracket placement orientation	Polyvinylpyrrolidone(25wt%) Sweet whey powder(25wt%) TiO2(25wt%) Food dye(25wt%)	Polyvinylpyrrolidone(25wt%) Sweet whey powder(25wt%) TiO2(25wt%) Food dye(25wt%)	Substantial Equivalence
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 designs with and without hook, conforming to ISO 27020:2010 Dentistry – Brackets and tube for Use in Orthodontics	Substantial Equivalence
Self-ligating mechanism	Yes	N/A	Different-
Design parts	Hook, Slot, Round home, base Door and marking	Hook, Slot, Round home, base and marking	Substantial Equivalence
Bracket In-out(mm)	0.65 to 1.08	0.56 to 1.45	Substantial Equivalence
Bracket Torque(°)	-22 to +17	-22 to +17	Substantial Equivalence
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

[S-Line™ vs. DAMON 4Clear (K081415)]

S-Line™ Orthodontic Ceramic bracket is a self ligating type, same as DAMON 4Clear (K081415), the reference device. The following comparison table is presented to demonstrate substantial equivalence.

	Candidate Device	Reference Device	Substantial Equivalence Analysis
510(k) Number	K182193	K081415	-
Device Name	S-Line™	DAMON 4Clear	-
Common Name	Orthodontic Ceramic bracket	Orthodontic Ceramic bracket	-
Manufacturer	BIOCETEC CO., LTD.	Ormco Corporation	-
Indication for Use	S-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.	DAMON 4Clear is a ceramic bracket system intended to aid in the movement of patient teeth during orthodontic treatment.	Substantial Equivalence
Material composition of Bracket	Polycrystalline Alumina	Polycrystalline Alumina	Substantial Equivalence
Material composition of Door	Polycrystalline Alumina	Polycrystalline Alumina	Substantial Equivalence
Material composition of snap ring & pin	300 Series Stainless Steel	-	Different
Material composition of colorants for bracket placement orientation	Polyvinylpyrrolidone(25wt%) Sweet whey powder(25wt%) TiO2(25wt%) Food dye(25wt%)	-	Different
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
Self-ligating mechanism	Yes	Yes	Substantial Equivalence
Design parts	Hook, Slot, Round home, base and marking	Hook, Slot, Round home, base and marking	Substantial Equivalence
Bracket In-out(mm)	0.65 to 1.08	0.51 to 1.14	Different
Bracket Torque(°)	-22 to +17	-11 to +22	Different
Bracket Angulation(°)	0 to 11°	2 to 9°	Different
Available slot sizes	0.018 / 0.022 inch	0.018 / 0.022 inch	Substantial Equivalence
Orientation marking	Yes	Yes	Substantial Equivalence

Single 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

S-Line™ Orthodontic Ceramic bracket does not have a new intended use. However, there are differences in some parameters (Material composition of door, Material composition of colorants for bracket placement orientation, Bracket In-out, Bracket Torque, Bracket Angulation) between S-Line™ Orthodontic Ceramic bracket and DAMON 4Clear, the reference device.

Material compositions for door and snap ring pin of the subject device are Polycrystalline Alumina(100%) and 300 Series Stainless Steel, respectively. Materials used to S-Line™ are identical to C-Line™ (K163467), the primary predicate device.

Also the colorants for bracket placement orientation are the same as the primary predicate device, C-Line ™ (K163467): Polyvinylpyrrolidone(25wt%), Sweet whey powder(25wt%), TiO2(25wt%), Food dye(25wt%).

S-Line ™ is a self ligating mechanism type which is the same as the reference device, DAMON 4Clear.

The bracket in-out, torque and angulation are identical to the primary predicate device whereas there are differences between S-Line™, the subject device and DAMON 4Clear, the reference device. The bracket in-out of the subject device is 0.65 to 1.08 mm whereas the range for the reference device is between 0.51 to 1.14 mm. The bracket torque for the subject device is -22 to +17° wider than the reference device's-11 to +22°. The bracket angulation for the subject device 2 to 11° whereas the reference device's range 2 to 9°.

The differences, however, do not impact the safety and effectiveness as demonstrated in the performance tests.

Transbond™ XT (K073697) is included as a reference device as it is the bonding agent used to demonstrate substantial equivalence in performance testing.

9. Performance Tests (Non-clinical)

Non-clinical performance tests were in accordance with:

-. ISO 27020:2010 Dentistry - Brackets and tubes for use in Orthodontics
-. ISO 11405:2015 Dentistry - Testing of adhesion to tooth structure
-. ISO 29022:2013 Dentistry – Adhesive – Notched edge sheer bond strength test.

The following tests for performance comparison between the subject and the reference device have been conducted; wire slot torque strength, shear bond strength, bracket removal test, wire slot drag strength, door pull-out strength and the adhesive strength bonding testing.

Wire Slot Torque test demonstrates stability to withstand the torque force from wire.
Shear Bonding test showed the bond strength of brackets.
The removal test with plier showed stability of brackets de-bonding performance from the enamel surface.
Wire Drag Test measured the friction between wire and bracket slot.
Door Pull-Out Test measured tensile force at the moment of the fracture from the orthodontic wire.
Also the adhesive strength bonding testing was conducted to study bonding of an adhesive to tooth structure or a bracket.

The result of the performance comparison test demonstrates that S-Line™ Orthodontic Ceramic bracket is substantially equivalent to the reference device.

Along with the above tests, biocompatibility testing accordance with ISO 10993-1 has been conducted for S-Line ™ orthodontic ceramic bracket.

Human Contact Part	Test Item	Test Report Number	Test Standard	Test Result
Mucosal membrane	Cytotoxicity	CR587171211	ISO 10993-5	Non-cytotoxic
	Mucosal Irritation		ISO 10993-10	None Irritation
	Skin Sensitization		ISO 10993-10	Do not show any hypersensitivity

The biocompatibility test results demonstrated that there is no new concern in the cytotoxicity, sensitization, irritation, genotoxicity and no subchronic toxicity.

10. Conclusions:

Based on the information provided in this premarket notification, BIO CETEC CO., LTD. concludes that the S-Line™ Orthodontic Ceramic bracket is substantially equivalent to the primary predicate device and the reference device as described herein.