June 6, 2023

Biocetec Co., Ltd
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K231635
Trade/Device Name: A-Line Advanced
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM
Dated: May 29, 2023
Received: June 5, 2023

Dear Dave Yungvirt:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231635

Device Name
A-Line Advanced

Indications for Use *(Describe)*
A-Line Advanced 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

The following 510(k) summary is being submitted as required by 21 CFR Part 807.92;

1.1 Submitter:

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Date Prepared: 23 May, 2023

1.2 Device Identification

Device Trade Name	A-Line Advanced
Common Name	Orthodontic Ceramic bracket
Classification Name, Number	Bracket, Ceramic, Orthodontic (21 CFR 872.5470)
Device Classification	II
Product Code	NJM

1.3 Predicated or legally marketed devices which are substantially equivalent

Predicated device: K182193, "S-Line", manufactured by "BIOCETEC CO., LTD."

1.4 Device Description

This orthodontic bracket is made of polycrystalline ceramic and is used for the treatment of malocclusion. It is designed to be attached to the surface of patients' teeth and be connected to the orthodontic wire in order to apply physical pressure on the tooth movement. Each model differs in size and dimension, color identification as they are attached to the tooth surface corresponding to 20 of the 28 permanent teeth.

[Principle of operation]
The orthodontic bracket is a device that evenly arranges the teeth of malocclusion and, as a device, moves the teeth to the position of the prescription applied to the bracket through an orthodontic wire.

[Bracket Type]

Standard Type	Slot Type	Slot size(inch)
MBT	MBT022	0.022 X 0.028
Roth	Roth018	0.018 X 0.025

	Roth022	0.022 X 0.028

[Physical and Performance Characteristics]

Item	Reference Standards	Specification
Dimension	ISO 27020(2019)	-. Torque(±3°) -. Angulation(±3°) -. Offset (±3°) -. Slot length(±0.1 mm) -. Slot width(±0.1 mm) -. Slot depth(±0.1 mm) -. In-out(±0.1 mm)
Corrosion	ISO 22674(2016) ISO 10271(2020)	1.642 ± 0.157 ug/㎠ in 7 days
Hazardous elements	ISO 22674(2016)	-. Be : 0.00 wt % -. Cd : 0.00 wt % -. Pb : 0.00 wt % -. Ni : 36.59 wt %
Adhesion Test to tooth	ISO 11405(2015)	-. Mean±SD : 7.22 ± 2.34 MPa

1.5 Statement of Indication for use

A-Line Advanced 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.

1.6 Non-clinical Test Conclusion

Non-clinical performance tests were performed as followings:

[Biocompatibility Testing]

- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-14 Identification and quantification of degradation products from ceramics
- ISO 10993-15 Identification and quantification of degradation products from metals and alloys

Biocompatibility testing in accordance with ISO 10993-1 has been conducted for A-Line Advanced orthodontic ceramic bracket.

(1) Conducted Biocompatibility Testing Results
Cytotoxicity, Mucosal Irritation, Skin Sensitization, Acute systemic toxicity

Actually, A-Line Advanced has done the tests as follows:

Human Contact Part	Test Item	Test Report Number	Test Standard	Test Result	Laboratory
Mucosal	Cytotoxicity	MGK-2022-	ISO 10993-5	Non-cytotoxic	KTR(Korea

membrane		001004			Testing & Research Institute)
	Mucosal Irritation	MGK-2022-000223	ISO 10993-23	None Irritation	
	Skin Sensitization	MGK-2022-000224	ISO 10993-10	Do not show any hypersensitivity	
	Acute systemic toxicity	MGK-2022-000225	ISO 10993-11	Do not show any acute systemic toxicity	

(2) Justification for not conducting the Subacute/subchronic toxicity, Genotoxicity, Implantation, Chronic toxicity test
Biological safety was evaluated by conducting tests on cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute toxicity depending on contact area and contact duration. But, Subacute/subchronic toxicity, Genotoxicity, Implantation, Chronic toxicity Tests were not conducted due to the reasons as follows;
Subacute/subchronic toxicity, Genotoxicity, Implantation, Chronic toxicity were evaluated through the biological evaluation written by an expert [Seoul National University Dental Hospital Dental Material & Device Evaluation Center]. The Biological Assessment Report (CR2208098) includes the biological evaluation of Subacute/subchronic toxicity, Genotoxicity, Implantation, Chronic toxicity. Required Subacute/subchronic toxicity, Genotoxicity, Implantation, Chronic toxicity Test have been substituted by the result of this evaluation.

The biocompatibility test results demonstrated no new concern in the cytotoxicity, sensitization, irritation, acute systemic toxicity, subacute/subchronic toxicity, genotoxicity, implantation, and chronic toxicity.

The result of the biocompatibility test demonstrates that A-Line Advanced Orthodontic Ceramic bracket is substantially equivalent to the predicate device.

[Performance Testing]
- ISO 27020 Dentistry - Brackets and tubes for use in orthodontics
- ISO 22674 Dentistry - Metallic materials for fixed and removable restorations and appliances
- ISO 10271 Dentistry - Corrosion test methods for metallic materials
- ISO/TS 11405 Dentistry - Testing of adhesion to tooth structure

Along with the above biocompatibility testing, Performance Testing has been conducted for A-Line Advanced orthodontic ceramic bracket.

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 A-Line Advanced Orthodontic Ceramic bracket is substantially equivalent to the predicate device.

Therefore, the above discussion made us conclude that A-Line Advanced is substantially equivalent to the predicate devices for its intended use.

4.7 Clinical Test Conclusion

Clinical testing was not required for this submission.

4.8 Technical Characteristics and Substantial Equivalence

The Orthodontic Ceramic bracket(A-Line Advanced) is substantially equivalent to Orthodontic Ceramic bracket(S-Line) (K182193). The following comparison table is presented to demonstrate substantial equivalence.

The Orthodontic Ceramic bracket(A-Line Advanced) does not have a new intended use. It shows equivalent specifications with the predicate devices in most of parameters. However, there are differences in some parameters [Material composition of Bracket, Material composition of Door, Bracket In-out(mm), Bracket Torque(°), Bracket Angulation(°)] between Orthodontic Ceramic bracket(A-Line Advanced) and Predicate Device(K182193).

As identification dot is to facilitate easy identification for user when locating Orthodontic Ceramic bracket(A-Line Advanced) on teeth, it does not affect effectiveness or safety even though there is a difference in material composition of colorants for bracket placement orientation. In addition, it is confirmed that the difference of Bracket In-out & Bracket Torque & Bracket Angulation does not affect effectiveness or safety through Bench Test(*) between the Orthodontic Ceramic bracket(A-Line Advanced) and Predicate Device.

In almost all aspects, the Orthodontic Ceramic bracket(A-Line Advanced) is substantially equivalent in its effectiveness and safety to the predicate devices.

Table 1. General Device Characteristics Comparison Table

	Candidate Device	**Predicate 1**	**Substantial Equivalence Analysis**
510(k) Number	Pending	K182193	-
Device Name	A-Line Advanced	S-Line	-
Common Name	Orthodontic Ceramic bracket	Orthodontic Ceramic bracket	-
Manufacturer	BIOCETEC CO., LTD.	BIOCETEC CO., LTD.	-
Indication for Use	A-Line Advanced 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.	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.	Same as predicate
Material composition of Bracket	Polycrystalline Alumina ※ Primer Polymer : 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid & Acetone	Polycrystalline Alumina	No significant difference : The subject device passed the test criteria for the biological evaluation according to the recognized consensus

			standard ISO 10993-1
Material composition of Door	Ni-Co-Cr-Mo Alloy	Polycrystalline Alumina	No significant difference : The subject device passed the test criteria for the biological evaluation according to the recognized consensus standard ISO 10993-1.
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%)	Same as predicate
Transparency	Half-transparency	Half-transparency	Same as predicate
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	Same as predicate
Self-ligating mechanism	Yes	Yes	Same as predicate
Design parts	Hook, Slot, Round home, base and marking	Hook, Slot, Round home, base and marking	Same as predicate
Bracket In-out(mm)	0.7 to 1.24	0.65 to 1.08	No significant difference : The subject device passed the test criteria for the bench test according to the recognized consensus standard ISO 27020.
Bracket Torque(°)	-30 to 17	-22 to +17	No significant difference : The subject device passed the test criteria for the bench test according to the recognized consensus standard ISO 27020.
Bracket Angulation(°)	0 to 13	0 to 11	No significant difference : The subject device passed the test criteria for the bench test according to the recognized consensus standard ISO 27020.
Available slot sizes	0.018 / 0.022 inch	0.018 / 0.022 inch	Same as predicate
Orientation marking	Yes	Yes	Same as predicate
Single use	Yes	Yes	Same as predicate

Non-Sterile Packaging	Yes	Yes	Same as predicate
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Same as predicate
Anatomical Site	Teeth	Teeth	Same as predicate
Location of Use	Use only by professional orthodontists	Use only by professional orthodontists	Same as predicate
Bio-compatibility	All user directly contacting materials are compliance with ISO10993 requirements.	All user directly contacting materials are compliance with ISO10993 requirements.	Same as predicate

(*) Comparison of the property of two orthodontic brackets by bench test

Orthodontic Ceramic bracket(A-Line Advanced) and the predicate device(S-Line (K182193)) have identical indication for use statements and the same intended use.

The 510(K) Documentation also includes data from bench testing to evaluate the performance of Orthodontic Ceramic bracket(A-Line Advanced) to the predicate device. The properties evaluated include wire slot torque test, shear bond strength test, and bracket removal test, wire slot drag test and door pull-out test.

Although the subject device and predicate device are no significant differences in some parameters[Material composition of Bracket, Material composition of Door, Bracket In-out(mm), Bracket Torque(°), Bracket Angulation(°)], the differences do not affect the substantial equivalence of the subject device when compared to the predicate device.

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

1.9 Conclusion

Based on the testing results, BIOCETEC CO., LTD. concludes that the subject device is substantially equivalent to the predicate device.

1.10 Declarations

This summary includes only information that is also covered in the body of the 510(k).
This summary does not contain any puffery or unsubstantiated labeling claims.