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

May 9, 2017

Koroad America
% Joyce Bang
President
Provision Consulting Group Inc.
3248 Willow Hollow Rd
Chino Hills, California 91709

Re: K163117
Trade/Device Name: Alpha Pure
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: March 15, 2017
Received: April 6, 2017

Dear Joyce Bang:

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,

Michael J. Ryan -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163117

Device Name
Alpha Pure

Indications for Use *(Describe)*

This device is intended for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only.

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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K163117

510(k) Summary

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

Submitter:
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Official Correspondent:
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Submission Date: 5/04/2017
Submission Type: Traditional 510(k)
Trade/Proprietary Name: Alpha Pure
Device Common Name: Bracket, Ceramic, Orthodontic
Regulation Class: II
Product Code: NJM
Regulation Number: 21 CFR 872.5470
Predicate Device: Sapphire Ceramic Bracket (K073045)

Device Description:
The proposed device, Alpha Pure, consists of ceramic orthodontic brackets which are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontics wire, to alter the tooth position. The ceramic bracket is produced using AI203, translucent polycrystalline aluminum oxide (99.99%). The brackets are bonded to the teeth with commercially available materials and linked together by "arch wire" that applies steady, gentle pressure to produce desired tooth movement.

Indications for Use:
This device is indicated for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:
* Indications for use
* Technological characteristics
* Performance properties

Summary of the technological characteristics compared to the predicate device
The subject device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table provided below.

	Subject device	Predicate
Device Name	Alpha Pure	Sapphire Ceramic Bracket
Manufacturer	Luce castle Co., Ltd.	Ortho Technology Inc.
510(k) number	N/A	K073045
Indications for Use	This device is indicated for the orthodontic movement of teeth. It is used temporarily and is removed after	This device is indicated for the orthodontic movement of teeth. It is used temporarily and is removed after

	orthodontic treatment has been completed. The devices are intended to be single use only.	orthodontic treatment has been completed. The devices are intended to be single use only.
Material	Aluminum Oxide	Aluminum Oxide
Biocompatibility	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993
Maxillary Torque (mm)	-21 to +17	-22 to +17
Maxillary Angulation	0 – 9	0 - 11
Slot	0.018", 0.022"	0.018", 0.022"
Transparency	Half-transparency	Half-transparency
Color	White, same as tooth color	White, same as tooth color
Indication system	Colored-dot	Colored-dot
Design	Tie wings for ligature, Hook, Archwire Slot, Round home, base and identification marks for placement	Tie wings for ligature, Hook, Archwire Slot, Round home, base and identification marks for placement
	Hooks for ligation, for additional tooth movement, Molded ceramic body with rounded corners and edges, Slot to hold orthodontic wires	Hooks for ligation, for additional tooth movement, Molded ceramic body with rounded corners and edges, Slot to hold orthodontic wires
Single Use	Yes	Yes
Non-Sterile Packaging	Yes	Yes

Non-Clinical Study performance

The subject device was found to be in compliance with biocompatibility. The standards which have been applied to the biocompatibility study were ISO 10993 Biological evaluation of medical devices Part 1 – Evaluation and testing in the risk management process, Part 4 - Selection of tests of interactions with blood, Part 5 – Tests for in vitro cytotoxicity and Part 10 – Tests for irritation and delayed-type hypersensitivity.

Substantial Equivalence Discussion

The subject device is substantially equivalent to the predicate device in it's a variety of characteristics stated in the comparison table provided below.

Substantial Equivalence Comparison Chart and Discussion

	Subject device	Predicate
Device Name	Alpha Pure	Sapphire Ceramic Bracket
Manufacturer	Luce castle Co., Ltd.	Ortho Technology Inc.
510(k) number	N/A	K073045
Indications for Use	This device is indicated for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only.	This device is indicated for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only.
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Transparency	Half-transparency	Half-transparency
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	Hooks for ligation, for additional tooth movement, Molded ceramic body with rounded corners and edges, Slot to hold orthodontic wires	Hooks for ligation, for additional tooth movement, Molded ceramic body with rounded corners and edges, Slot to hold orthodontic wires
Single Use	Yes	Yes
Non-Sterile Packaging	Yes	Yes

<u>Design Comparison:</u>

The subject device and its predicate device both incorporate specific torques, angulations, and distal offset dimensions, along with archwire slots that are designed to accommodate the correct size archwire (typically .018" or .022" thick). They both feature tie wing undercut spaces for orthodontic ligatures, have a molded ceramic bracket bodies with rounded corners and edges for patient comfort, and rounded hooks on the tie wings to accommodate ligation during orthodontic treatment. They both have bases that are designed to provide maximum adhesion to the tooth while still allowing for easy and complete removal when necessary. However, there are slight differences on the range of Maxillary Torque and Maxillary Angulation between the subject and the predicate. While the ranges are not identical, these differences are not expected to affect the overall performance of the device since they are still within the range of what is typically observed for orthodontic brackets.

Material Comparison:
Like its predicate, the subject devices are manufactured from polycrystalline alumina (ceramic) material, which has a well-documented history of biocompatibility within the oral environment. Like its predicate, the subject devices do not incorporate medicinal substances, tissues, or blood products. They are delivered non- sterile to the end user and are intended to be used once by a single patient.

Indications For Use Comparison:
The subject and predicate device have both same indications for use. They both are indicated for the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single use only.

Conclusion:
The subject device is designed, manufactured and engineered to be substantially equivalent to the predicate with respect to its equivalent indications for use, technological characteristics, device design, materials, performance and biocompatibility. Although there are slight differences in the range of Maxillary Torque and Maxillary Angulation between the subject and predicate devices, they both are within the range of what is typically observed for orthodontic brackets.

Thus, the subject device Alpha Pure is demonstrated to be substantially equivalent to the predicate device.