November 4, 2019

Orthosun Co., Ltd.
% Peter Chung
Representative
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K190608
Trade/Device Name: Mei Ceramic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM
Dated: August 5, 2019
Received: August 13, 2019

Dear Peter 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. 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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K190608

Device Name

Orthodontic Ceramic Bracket

Indications for Use *(Describe)*

This Mei Ceramic Bracket 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.

Orthosun.Co., Ltd.
www.orthosun.co.kr

510(k) Summary [as required by 807.92(c)]

I. SUBMITTER

a) Company: Orthosun Co., Ltd.
b) Address: 2F, 112, Pyeongni-gil, Gyeyang-gu, Incheon, 21008, Republic of Korea
c) Tel. : 82-32-545-2825
d) Fax : 82-32-554-2879
e) President of Company: Mr. Woo-sik Kim
f) Contact Person : Mr. Peter Chung, US designated agent
g) Contact Person Telephone: 412-687-3976
h) Contact Person Address: 300, Atwood Street, Pittsburgh, PA, 15213, USA
i) Submission Date: February 18, 2019

II. DEVICE

a) Trade Name : Mei Ceramic Bracket
b) Common Name : Orthodontic Ceramic Bracket
c) Classification Name : bracket, ceramic, orthodontic
d) Product Code : NJM
e) Regulation Number : 872.5470
f) Class of device : Class II
g) Panel : Dental

III. PREDICATE DEVICE

a) Primary Predicate Device:
K073045, Sapphire Ceramic Bracket / Ortho Technology Inc.

IV. DEVICE DESCRIPTION

The proposed device, Mei Ceramic Bracket, 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.

V. INDICATIONS FOR USE

This Mei Ceramic Bracket 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.

VI. SUBSTANIAL EQUIVALNECE COMPARISON

The Mei Ceramic Bracket is similar designs and dimensions, and has the same material, intended use, and technological characteristics as the identified primary predicate device (K073045). When compared with predicate device, no new questions of substantial equivalence have been

raised for the Mei Ceramic Bracket.

	SUBJECT Device	**Primary PREDICATE Device K073045**
Manufacturer	**Orthosun Co., Ltd.**	**Ortho Technology Inc.**
Common Name	Orthodontic Ceramic Bracket	Orthodontic Ceramic Bracket
Trade Name	Mei Ceramic Bracket	Sapphire Ceramic Bracket
Indications for Use/ Intended Use	Mei Ceramic Bracket 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.
Clarity	Translucent	Translucent
Bracket Design	MBT, ROTH designs without hook	MBT, ROTH designs with and without hook
Torque	-21° to 17°	-22° to +17°
Angulation	Up to +9°	Up to +11°
Available Slot Size	.018", .022"	.018", .022"
Material	Alumina (Al_2O_3)	Alumina (Al_2O_3)
Colour	White, same as tooth color	White, same as tooth color
Indication System	Colored-dot	Colored-dot
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1
Single Use	yes	yes
Non-Sterile Packaging	yes	yes

VII. NON-CLINICAL TEST DATA

Non-clinical performance data included testing results for dimension, Bracket removal test, Shear bonding test, Torque test, and Wire drag test. The testing analysis shows that Mei Ceramic Bracket perform comparably to the predicate devices.

Biocompatibility assessment and testing was performed using standard risk assessment techniques and in consideration of FDA and internationally recognized guidance's.

Mei Ceramic Bracket was inspected and met the dimensions itemized in ISO 27020, Dentistry – Brackets and tubes for use in orthodontics.

VIII. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification concludes that the Mei Ceramic Bracket is safe and effective and substantially equivalent to the predicate device as described herein.