October 9, 2020

Luce Castle Co., Ltd.
% Joyce Bang-Kwon
CEO
Provision Consulting Group Inc.
100 N. Barranca St Suite 700
West Covina, California 91791

Re: K201038
Trade/Device Name: Luce Ceramic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: July 6, 2020
Received: July 13, 2020

Dear Joyce Bang-Kwon:

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 “Nandu” Nandkumar, Ph.D.
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)*

K201038

Device Name

Luce Ceramic Bracket

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.

510(K) SUMMARY

510(k) Summary - K201038

This 510(k) Summary is being submitted in accordance with requirement of 21 CFR part 807.92

Submitter:

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Device Information:

Trade/Proprietary Name: Luce Ceramic Bracket
Device Common Name: Bracket, Ceramic, Orthodontic Regulation Class: II
Product Code: NJM
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Primary Predicate : Alpha Pure (K163117)
Date prepared: 10/9/2020

General Description

The proposed device, Luce 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.

Indication 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	Primary Predicate Deivce	Substantial Equivalence Discussion
Device Name	Luce Ceramic Bracket	Alpha Pure	N/A
Manufacturer	Luce castle Co., Ltd.	Luce castle Co., Ltd.	Identical
510(K) Number	K201038	K163117	N/A
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.	Identical
Material	Aluminum Oxide	Aluminum Oxide	Identical
Biocompatibility	Meets the applicable requirement of ISO 10993	Meets the applicable requirement of ISO 10993	Identical
Maxillary Torque (mm)	-21 to +17	-21 to +17	Identical
Maxillary Angulation	0 – 9	0 – 9	Identical
Slot	0.018″, 0.022″	0.018″, 0.022″	Identical
Transparency	Half-transparency	Half-transparency	Identical
Indication system	Colored-dot	Colored-dot	Identical
Design	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	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	Identical
Single Use	Yes	Yes	Identical
Non-Sterile Packaging	Yes	Yes	Identical

Non-Clinical Study Performance

Biocompatibility testing were conducted on the predicate devices, Alpha Pure(K163117). Since the materials, manufacturing process, packaging materials and methods are identical between the subject and predicate devices, the test reports can be leveraged for the subject device. Subject device and the predicate(K163117) are Identical.

Conclusion

The subject device performs as well as the predicate device listed above in orthodontic treatment and they are designed, manufactured and engineered to be substantially equivalent to the predicate with respect to indications for use, technological characteristics, device design, materials, performance and biocompatibility. Thus, the overall performance of the subjectdevice is expected to be substantially equivalent to the predicate device.