DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Liaoning Upcera Co.,ltd
Charles Shen
Official Correspondent
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

January 12, 2017

Re: K162323
Trade/Device Name: Tooth Shade Resin Material
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: August 17, 2016
Received: December 13, 2016

Dear Charles Shen:

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,

Susan Runner DDS, MA

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)*
K162323

Device Name
"Hyramic CAD/CAM Restorative"

Indications for Use *(Describe)*
"Hyramic CAD/CAM Restorative" is used for dental restorations, such as full crowns, inlays/onlays and veneers.

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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Section 5: 510(k) Summary:

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

5.1 Submitter & Foreign Manufacture Identification

Liaoning Upcera Co., Ltd
No.122 Xianghuai Road, Economic Development Zone, Benxi, Liaoning, China
Tel： (086)-24-45565006
Submitter's FDA Registration Number：3010582952
www.upcera-dental.com

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: January 11, 2017

5.4 Device Name:

Proprietary Name:	Hyramic CAD/CAM Restorative
Common Name:	Dental material, filling/restorative, polymer based
Classification Name:	Tooth Shade Resin Material
Classification Regulation:	21 CFR 872.3690
Product Code:	EBF
Class:	Class 2
Panel:	Dental

5.5 Predicate Device Information:

The "Hyramic CAD/CAM Restorative" described in this premarket notification are substantially equivalent to:

(1) K110131, "Lava Ultimate CAD/CAM Restorative", manufactured by "3M Company", at St. Paul, MN

5.6 Device Description:

"Hyramic CAD/CAM Restorative" consists of inorganic filler and polymer material to form a homogeneous solid block material. The inorganic filler is derived from glass powders, while the resin is derived from methacrylate co-polymer (UDMA，TEGDMA, and BisGMA). The formed blocks have a microstructure of inorganic materials embedded in a highly cured resin matrix. The unique combination of the two materials creates a uniform hybrid, which lends the positive physical properties of each individual material to the other.

The material has been processed through various molding techniques – into their final net shapes. These blanks are then further fabricated into various prosthetic dental devices intended for use in the production of dental restorations such as full crowns, inlays/onlays and veneers. The performance of formed Hyramic CAD/CAM Restorative conforms to *ISO 10477, Dentistry — Polymer-based crown and bridge material.*

"Hyramic CAD/CAM Restorative" is hybrid ceramic/resin dental blanks designed for the manufacture of dental prosthetic devices. The dental prosthetic devices are fabricated by CAD/CAM machining processes. All prosthetic dental devices are intended for single use applications. At the dental lab, the blanks are held to the CAD/CAM machine which is used to machine to the final dental restoration. Unlike conventional ceramic restorations, customization and glaze firing is not necessary for Hyramic CAD/CAM Restorative.

"Hyramic CAD/CAM Restorative" is supplied in different shapes, such as blocks, discs, rods, or customer ordered shapes. It is also supplied in the combinations of twenty one different colors, two different translucencies, and two different aesthetic effects (single and multilayer).

The different colors are originated from the different constituent of color additives; the different translucencies are originated from different content of BisGMA, and the different aesthetic effects are originated from the different padding method used in the process of molding.

5.7 Indications for Use:

"Hyramic CAD/CAM Restorative" is used for dental restorations, such as full crowns, inlays/onlays and veneers.

5.8 Summary of Device Testing:

Bench testing was performed per ISO 10477:2004 and internal procedures to ensure that the "Hyramic CAD/CAM Restorative" met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalence of the materials that are used.

5.9 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Subject Device	Predicate Device (K110131)
Indication for Use	"Hyramic CAD/CAM Restorative" is used for dental restorations, such as full crowns, inlays/onlays and veneers.	The product is indicated for inlays, onlays, veneers, and full crown restorations, including crowns on implants.
Basic Design	Blocks, disc, and rod	Blocks, disc, and rod
Materials	Glass powder, Copolymer of UMDA, TEGDMA, and BisGMA	SiO_2, ZrO_2, Copolymer of SiO_2, ZrO_2, Copolymer of UMDA, TEGDMA, BisEMA, and BisGMA
Microstructure	Resin-ceramic composite	Resin-ceramic composite
Processing	Mixed at room temperature and cured at elevated temperatures	Mixed at room temperature and cured at elevated temperatures
Curing Mechanism	Heat Induced	Heat Induced
Dimension	Various	Various
Single Use	Yes	Yes
Feature	Twenty one colors, two translucencies, and two aesthetic effects	Various colors and translucencies
Sterile	Non-sterile	Non-sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices.
The minor differences do not raise any safety and efficacy concerns.

5.10 Comparison of Performance with Predicate Device

Performance testing was performed on the subject device and results were compared with predicate device. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 10477, and results met all relevant requirements in the test standard. Test results on flexural strength, water absorption, and solubility in water of the subject device are very similar to the predicate device.

Biocompatibility tests were conducted following the recommended procedures outlined in the FDA recognized consensus standard of ISO 10993, and results from the subject

device met all relevant requirements in the test standards, and are comparable to the predicate device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that “Hyramic CAD/CAM Restorative” and its predicate devices have the identical indications for use, similar composition and biocompatibility, similar manufacturing process, and similar performance.

The difference between the “Hyramic CAD/CAM Restorative” and their predicate device do not raise any question regarding its equivalence.

“Hyramic CAD/CAM Restorative”, as designed and manufactured, is equivalent to its predicate device, and therefore is substantially equivalent as its predicate device.