May 31, 2024

Anhui Miisen Intelligence Technology Co., Ltd.
℅ Jinfeng Ning
Manager
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K240912
Trade/Device Name: Dental Zirconia Block (Models HT-plus, ST, SHT, UT, 3D-Pro)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 3, 2024
Received: April 3, 2024

Dear Jinfeng Ning:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240912

Device Name

Dental Zirconia Block (Models HT-plus, ST, SHT, UT, 3D-Pro)

Indications for Use *(Describe)*

"Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" is intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist. All blanks are processed through dental laboratories or by dental professionals

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.

K240912

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Anhui Miisen Intelligence Technology Co., Ltd. January 14, 2024
No. 6 Building, South Huoyanshan Road, Economic Development, Zone
Fanchang District, Wuhu City, Anhui Province, China
Tel： (086)- 0553-2358187
Submitter's FDA Registration Number： N/A

5.2 Contact Person

Primary Contact Person
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5.3 Date of Summary: March 25, 2024

5.4 Device Name:

Proprietary Name:	Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)
Common Name:	Dental Zirconia Ceramics
Classification Name:	Powder, Porcelain
Device Classification:	II
Regulation Number:	21 CFR 872.6660
Panel: General	Dental
Product Code:	EIH

5.5 Predicate Device Information:

K152175, "Dental Zirconia Blank for Aesthetic Restoration", manufactured by "Liaoning Upcera Co., Ltd."

5.6 Device Description:

"Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" is derived from zirconia powder that has been processed through various molding and sintering techniques – into their final net shapes. These blanks are then further fabricated into various prosthetic dental devices intended for use in the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers. The zirconia powder is composed of ZrO_2 , Y_2O_3, HfO_2 and other oxides. The performance of formed zirconia dental blanks conforms to *ISO 6872, Dentistry, Ceramic Materials.*

"Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" is ceramic dental blanks designed for the manufacture of ceramic 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. At the completion of the machining steps, the dental restoration is fired (i.e., sintered) in the oven to harden the ZrO_2 so that its final properties can be achieved.

"Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" is supplied in different shapes, such as blocks, disc, and semi-disc, or customer ordered shapes. It is also supplied in the combinations of 21 different colors, and single and multi-layer aesthetic effect.

The different colors are originated from the different constituent of color additives (such as Fe_2O_3, Er_2O_3); and the multilayer aesthetic effect is originated from the different padding method used in the process of dry pressing.

5.7 Indications for Use:

"Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" is intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist. All blanks are processed through dental laboratories or by dental professionals.

5.8 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 (K152175)
Indication for Use	"Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" is intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist. All blanks are processed through dental laboratories or by dental professionals	Is mainly used in prosthetic treatment. While the flexural strength of Dental Zirconia Ceramics after sintering is between 300-500 MPa, the product can be used for veneering, inlay, single crown, and substructure ceramic for three-unit prostheses not involving molar restoration; While the flexural strength of Dental Zirconia Ceramics after sintering is over 500 MPa, it can be used for veneering, inlay, single crown, and substrate ceramic for three-unit prostheses.
Basic Design	Blocks, disc, and semi-disc	Blocks, disc, and rod
Materials	Zirconia ($ZrO_2 + Y_2O_3 + HfO_2 \geq 98\%$) Inorganic pigments	Zirconia ($ZrO_2 + Y_2O_3 + HfO_2 \geq 98\%$) Inorganic pigments
Processing	Sintering at temperature > 1400 °C	Sintering at temperature > 1400 °C
Dimension	Various	Various
Single Use	Yes	Yes
Shade	Twenty one colors	Forty six colors
Aesthetic Effect	Two aesthetic effects: single and multilayer effect	Two aesthetic effects: single and multilayer effect
Translucency effect	Same translucency for all blocks	Three translucency effects. Each blank has a single translucency effect. Translucency is resulted from the small variations in Y_2O_3 content
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 effectiveness concerns.

5.9 Summary of Non-Clinical Testing:

Bench testing was performed per ISO 6872:2008 and internal procedures to ensure that the "Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" met its specifications.

The following tests were performed:
Uniformity
Freedom from Extraneous Materials
Radioactivity
Shrinkage factor
Sintered Density before Sintering
Sintered Density after Sintering
Expansion Coefficient
Sintered Flexural Strength
Chemical Solubility
Vickers hardness

All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalence of the materials that are used.

Per FDA's guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'", as well as ISO 10993-1: 2018, the following biocompatibility endpoints are considered:

Cytotoxicity (**ISO 10993-5)**
Irritation **&** Sensitization (**ISO 10993-10)**
Acute Systematic Toxicity (**ISO 10993-11)**
Subacute Subchronic Systematic Toxicity (**ISO 10993-11)**
Material Mediated Pyrogenicity (**ISO 10993-11)**
Implantation (**ISO 10993-6)**
Chronic Systematic Toxicity (**ISO 10993-11)**
Genotoxicity (**ISO 10993-3)**
Carcinogenicity (**ISO 10993-3)**

Biocompatibility was evaluated per ISO 19993-1: 2009, and it was found that the subject device is as biocompatible as the predicate device.

5.10 Summary of Clinical Study:

Clinical Study is not performed for this device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" and its predicate devices have similar indications for use, similar composition, and biocompatibility, similar manufacturing process, and similar performance.

The difference between the "Dental Zirconia Block (Model: HT-plus, ST, SHT, UT, 3D-Pro)" and their predicate device do not raise any question regarding its equivalence.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the subject device is respectively substantially equivalent to the predicate device.