April 12, 2024

Boston Micro Fabrication
% Eric Bannon
Sr. VP, Regulatory and Clinical Affairs
AlvaMed
935 Great Plain Ave
Suite 166
Needham, Massachusetts 02942

Re: K240419
Trade/Device Name: UltraThineer Zirconia Slurry (5Y-B)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 12, 2024
Received: February 13, 2024

Dear Eric Bannon:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240419

Device Name

UltraThineer Zirconia Slurry (5Y-B)

Indications for Use *(Describe)*

UltraThineer Zirconia Slurry is indicated for use by dental technicians in the construction of custom-made ceramic restorations. These include copings, crowns, inlays and onlays, veneers, and bridges (3-unit anterior bridges).

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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K240419

510(K) SUMMARY

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Submission Information

Date Summary Prepared:	27 January 2023
Name of Device:	UltraThineer Zirconia Slurry (5Y-B)
Device Classification Name:	Porcelain Powder for Clinical Use
Common or Usual Name:	Dental Zirconia Material
Classification:	Class II
Product Code:	EIH (21 CFR 872.6660)

Device Description

The UltraThineer Zirconia Slurry is a ceramic slurry intended for use in fabricating custom-made ceramic restorations using 3D printing and sintering processes.

There is a single formulation:

- Zirconia-5Y/BMF-5YZ-1.6B

The UltraThineer Zirconia Slurry is provided as a slurry contained in a sealed tamper-proof and opaque HDPE bottle, with product labeling. The bottle containing the slurry has dimensions of 3.5” in diameter and 7.75” in height and has a maximum volume of 0.75L.

For use, the slurry is poured into a vat inside the 3D printer for printing the dental veneer. After printing, the veneer is sintered to yield the final product. Each veneer will be custom fabricated on a named patient prescription basis on the order of a dentist.

Predicate Device

INNI-CERA by Aon Co., Ltd (K211308)

Valid Predicate Discussion

Inni-Cera was selected as the valid predicate device used to support the 510(k) submission because it was cleared using well-established methods. Inni-Cera was the only valid predicate device that could be identified which meets the expected predicate performance. After conducting a search on the Manufacturer and User Facility Device Experience (MAUDE) Database, Medical Device Reporting (MDR), MedSun Reports Database, Medical Device Safety and CBER Safety & Availability (Biologics) and Recall Database websites it was found that there are no known unmitigated use-related or design safety issues and the predicate device has not been subject to a design-related recall.

Table 1: Valid Predicate Device

Valid Predicate Device	**A - Well established methods**	**B - Meets or exceeds expected predicate performance**	**C - Unmitigated use-related or design-related safety issues**	**D – Associated design-related recall**
Inni-Cera	**Used relevant methods that were published in the public domain.**	**History of Safe use, established due to duration of device on the market**	**No known unmitigated use-related or design related safety issues**	**No design-related recall identified**

Indications for Use

UltraThineer Zirconia Slurry is indicated for use by dental technicians in the construction of custom-made ceramic restorations. These include copings, crowns, inlays and onlays, veneers, and bridges (3-unit anterior bridges).

Table 2: Comparison of Predicate Device and Subject Device

Contents	**Subject Device**	**Predicate Device**
Device:	UltraThineer Zirconia Slurry (5Y-B)	INNI-CERA
Manufacturer:	Boston Micro Fabrication	Aon Co., Ltd
510(k) Number:	Pending	K211308
Product Code(s):	EIH	EIH
Regulation Number & Description:	21 CFR 872.6660 Porcelain powder for clinical use	21 CFR 872.6660 Porcelain powder for clinical use
Classification	II	II
Device Description:	UltraThineer Zirconia Slurry device is intended for use in fabricating custom-made ceramic restorations using a 3D printer additive manufacturing process. There is one formulation, Zirconia-5Y/	INNI-CERA is intended for use in fabricating custom-made ceramic restorations using a 3D printer additive manufacturing process. It is a product that is used after fabricating and

Contents	Subject Device	Predicate Device
	BMF-5YZ-1.6B. It is a product that is used after fabricating and sintering with a mixture of zirconia powder and binder. The 3D printer used to fabricate the UltraThineer Zirconia Slurry is a photocuring lamination method using an STL file (dental restoration shape), which is irradiated with light in the strong UV region (420nm) to cure the photocurable mixture to form a model. This product corresponds to ISO 6872 Type I Class III. The material is used in a 3D printer, which prints the shape determined by an STL file converted from patients' teeth data. The 3D printer is not included with the product. The UltraThineer Zirconia Slurry device cannot be reused.	sintering with a mixture of zirconia powder and binder. The DLP 3D printer used to fabricate the INNI-CERA is a photocuring lamination method using an STL file (dental restoration shape), which is irradiated with light in the strong UV region (420nm) to cure the photocurable mixture to form a model. This product corresponds to ISO 6872 Type I Class III. The material is used in a 3D printer, which prints the shape determined by an STL file converted from patients' teeth data. 3D printer is not included with the product. INNI-CERA cannot be reused.
Indications For Use	UltraThineer Zirconia Slurry is indicated for use by dental technicians in the construction of custom-made ceramic restorations. These include copings, crowns, inlays and onlays, veneers, and bridges (3-unit anterior bridges).	INNI-CERA is indicated for use by dental technicians in the construction of custom-made ceramic restorations. Coping Crown Inlay & Onlay Veneer Bridge (3-unit anterior bridges)
ISO 6872 Type/ Classification:	Type 1/Class 3	Type 1/Class 3
Material Type	Slurry	Slurry
Provided Sterile:	Non-Sterile	Non-Sterile
Single-Use or Reusable:	Single Use	Single Use
Biocompatibility	According to EN ISO 10993-1	According to EN ISO 10993-1
Flexural Strength	>300 Mpa (meeting ISO 6872 requirements)	>300 Mpa (meeting ISO 6872 requirements)
Linear Thermal Expansion Coefficient	Mean linear thermal expansion coefficient within 0.5 x 10^{-6} K^{-1} of the value reported by the manufacturer	Unknown

Contents	Subject Device	Predicate Device
	(meeting ISO 6872 requirements)	
Chemical Solubility	< 100µg/cm² (meeting ISO 6872 requirements)	< 100µg/cm² (meeting ISO 6872 requirements)
Radioactivity	Activity concentration of uranium238 less than 1.0Bqg^{-1} (meeting ISO 6872 requirements)	Activity concentration of uranium238 less than 1.0Bqg^{-1} (meeting ISO 6872 requirements)
Production Type	3D Printing	3D Printing

Summary of Substantial Equivalence Comparison to the Predicate Device

The information provided for the subject device Indication for Use, Material, Biocompatibility, Flexural Strength, Linear Thermal Expansion Coefficient, Chemical Solubility and Radioactivity are equivalent to the predicate device, Inni-Cera cleared under K 211308. Both are zirconia slurry materials intended for 3D printing of dental implants followed by sintering. Both devices are composed of biocompatible material according to ISO 10993-1 and meet the requirements of ISO 6872. Both devices are intended for use by dental technicians in the construction of custom-made ceramic restorations.

Biocompatibility Testing

UltraThineer Zirconia Slurry (5Y-B) was evaluated according to ISO 10993-1. The results of these tests confirmed that it met the biocompatibility requirements. Biocompatibility testing included:

- Chemical Characterization
- Cytotoxicity
- Sensitization
- Oral Mucosal Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Non-Clinical Performance Data: Bench

The UltraThineer ceramic materials were evaluated according to ISO 6872:2015. The results of those test confirmed that the UltraThineer met all requirements of the standard. Testing included: Radioactivity; Flexural Strength; Linear Thermal Expansion Coefficient; Chemical Solubility; and; Shelf-Life Testing.

Performance Data: Clinical Testing

No clinical testing was applicable to this submission.

Conclusions

Like the predicate device originally cleared by the FDA, UltraThineer Zirconia Slurry has been shown to be safe through Bench Testing and Biocompatibility testing according to the above mentioned ISO standards. The data support substantial equivalence of the UltraThineer Zirconia Slurry subject device to the legally marketed predicate device.

The performance of the UltraThineer Zirconia Slurry meets the requirements of the non-clinical bench testing conducted to support substantial equivalence. Based on the available information, the subject device and the predicates are similar indication for use, material, performance data and biocompatibility.

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