February 27, 2023

Arumdentistry Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K223253
Trade/Device Name: Non-Sterile Zirconia Block (ARENA Star, Mont Blanc)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 2, 2023
Received: February 2, 2023

Dear April Lee:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223253

Device Name

Non-Sterile Zirconia Block (ARENA Star, Mont Blanc)

Indications for Use *(Describe)*

Non-Sterile Zirconia Block (Model name: ARENA Star, Mont Blanc) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, 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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510(K) Summary

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Device Information

- Trade Name: Non-Sterile Zirconia Block (ARENA Star, MontBlanc)
- Common Name: Powder, Porcelain
- Classification Name: Porcelain Powder For Clinical Use
- Product Code: EIH
- Panel: Dental
- Regulation Number: 21 CFR 872.6660
- Device Class: Class II
- Date Prepared: 02/24/2023

Predicate Device:

The subject device is substantially equivalent to the following predicate device:

- K190112, Non-Sterile Zirconia Block by FINE ADVANCED COMPOUND Co., Ltd.

Indication for Use:

Non-Sterile Zirconia Block (Model name: ARENA Star, MontBlanc) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Device Description:

Non-Sterile Zirconia Block (Model name: ARENA Star, MontBlanc), used to produce dental restoration to support designing computer for dental use and to process cutting as a manufacture unit, on which CAD/CAM system is applied for processing and sintering.

Summaries of Technological Characteristics & Substantial Equivalence Discussion

	Subject Device	**Primary Predicate**	**SE**
510(k) Number	K223253	K190112	
Company	ARUMDENTISTRY Co., Ltd.	FINE ADVANCED COMPOUND Co., Ltd.	
Device Name	Non-Sterile Zirconia Block	Non-Sterile Zirconia Block	
Model Name	ARENA Star, MontBlanc	Finebase, Montblanc, Trione HT, Trione C, Trione HT+	
Device Classification	POWDER, PORCELAIN/ Porcelain Powder For Clinical Use	POWDER, PORCELAIN/ Porcelain Powder For Clinical Use	Same
Product Code	EIH	EIH	Same
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	Same
Indications for Use	Non-Sterile Zirconia Block (Model name: ARENA Star, MontBlanc) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.	Non-Sterile Zirconia Block (Model name: Finebase, Montblanc, Trione HT, Trione C, Trione HT+) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.	Same
Principle of Operations	This partial sintered zirconia block is milled and finally sintered to make dental prosthesis	This partial sintered zirconia block is milled and finally sintered to make dental prosthesis	Same
Feature	Colored	Colored	Same
Shape	Discs	Discs	Same
Classification	Type II Class 5	Type II Class 5	Same
Standard Conformed	ISO 6872:2015	ISO 6872:2015	Same
Sterility	Non-sterile	Non-sterile	Same
Chemical Composition	ZrO2 with others	ZrO2 with others	Same
Crystal Morphology	Tetragonal	Tetragonal	Same
Flexural Strength	800Mpa	800 MPa	Same
Sintering temperature	1500 ± 50 ℃	1500 ± 50 ℃	Same
Contact Level	Surface device with permanent contact	Surface device with permanent contact	Same
Biocompatibility	Tested for Cytotoxicity, irritation, sensitization, acute systemic toxicity, no adverse reaction.	Tested for Cytotoxicity, irritation, sensitization, acute systemic toxicity, no adverse reaction.	Same
Similarities	The subject device and the primary predicate have similar indications, principle of operation, technological characteristics, and materials. They encompass the same range of physical and chemical properties. Therefore, both devices are substantial equivalent.		
Differences	The differences between the subject device and predicate are material supplier and addition of shades. The chemical composition of both devices are same but the material suppliers are different. Therefore, both devices are substantial equivalent.		

Non-Clinical Test Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device, including

- Performance Test per ISO 6872 Fourth Edition 2015-06-01, Dentistry - Ceramic Materials;
- Cytotoxicity per ISO 10993-5:2009;
- Intracutaneous Reactivity Test per ISO 10993-10:2010;
- Sensitization Test per ISO 10993-10:2010;
- Acute Systemic Toxicity per ISO 10993-11:2017.

Biocompatibility Evaluation

Biocompatibility evaluation of proposed Non-Sterile Zirconia Block was considered followed the FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," the ISO 10993 suite of standards. The biocompatibility for the proposed device was found to be substantially equivalent to the predicate devices as a result.

Sterilization Validation and Shelf-life

Proposed Non-Sterile Zirconia Block is delivered in non-sterile status and this device is unnecessary of sterilization prior to use. Therefore, sterilization validation was not considered.

Mechanical Properties

Proposed Non-Sterile Zirconia Block has been designed and tested in accordance with ISO 6872 Dentistry - Ceramic Materials. All tests have passed the evaluation criteria and met the requirement of product-specific ISO 6872 specifies for Class 5 dental ceramics. The mechanical properties were found to be substantially equivalent to the predicate devices as a result.

Clinical Test Conclusion

No clinical study is included in this submission.

Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be substantially equivalent to the predicate device.