July 10, 2025

ARUM Dentistry Co., Ltd.
Choi Won-Yi
Official Applicant
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
SOUTH KOREA

Re: K250063
Trade/Device Name: ARENA Star, Galaxy Star
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: July 1, 2025
Received: July 1, 2025

Dear Choi Won-Yi:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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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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)*
K250063

Device Name
ARENA Star, Galaxy Star

Indications for Use *(Describe)*
Non-Sterile Zirconia Block (Model name: ARENA Star, Galaxy Star) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers. All zirconia block 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.

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7. 510(K) Summary

Submitter

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Device Information

- Trade Name: ARENA Star, Galaxy Star
- Common Name: Powder, Porcelain
- Classification Name: Porcelain Powder For Clinical Use
- Primary Product Code: EIH
- Panel: Dental
- Regulation Number: 21 CFR 872.6660
- Device Class: Class II
- Date Prepared: 1/10/2025

Predicate Devices

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

Primary Predicate

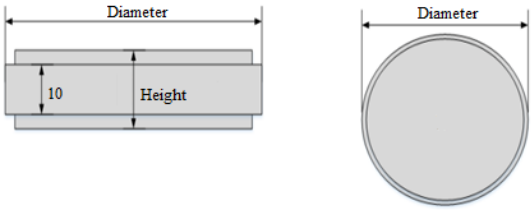
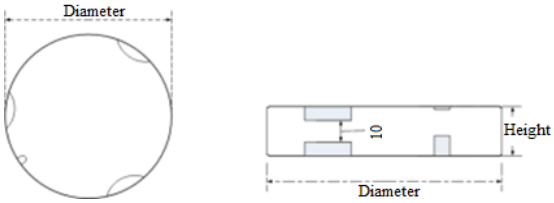
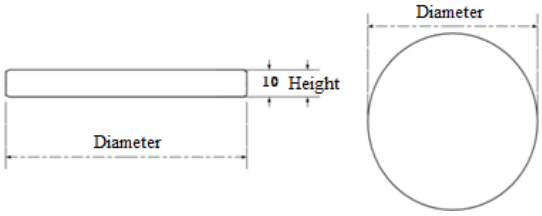
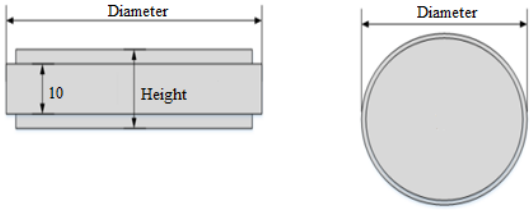
- K223253 Non-Sterile Zirconia Block (ARENA Star, MontBlanc) by Arumdentistry Co., Ltd.

7.1. Device Description

7.1.1. General Description

Non-Sterile Zirconia Block (Model name: ARENA Star, Galaxy Star) 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. After application, this material cannot to be reused for fabrication.

Definition of Brand name & Series name

Model name	Shape	Series name	Diameter
Arena Star		UML5-WR Series AML5-WR Series GUML5-WR Series GAML5-WR Series	98.5 mm
		UML5-ZR Series	98.5 mm
Galaxy Star		GalaxyStar-WR-10 GalaxyStar-WR-10 A1~D4	98.5 mm
		GalaxyStar- WR Series GalaxyStar HT series	98.5 mm

Indication for Use

Non-Sterile Zirconia Block (Model name: ARENA Star, Galaxy Star) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers. All zirconia block are processed through dental laboratories or by dental professionals.

Principle of Operation

This product is a zirconia block, a ceramic material used to manufacture dental restorations such as artificial teeth, crowns and veneers. It is a ceramic material that is cut by a dental computer-aided design and manufacturing unit. It is processed using a CAD/CAM system and sintered go through.

Materials

List of Raw materials of the Device

No	Raw material name	Components	CAS No	Esposure or esposure limited(wt%)
1	Zirconium oxide A (T4Y-010OP)	Zirconium Oxide (ZrO2)	1314-23-4	84.0-94.0wt%
2		Yttrium oxide (Y2O3)	1314-36-9	6.0-9.0wt%
3		Poly (vinyl alcohol)	9002-89-5	≤6.0wt%
4	Zirconium oxide B (T4Y-010DP)	Zirconium Oxide (ZrO2)	1314-23-4	84.0-94.0wt%
5		Yttrium oxide (Y2O3)	1314-36-9	6.0-9.0wt%
6		Ferric oxide	1332-37-1	≤0.5wt%
7		Poly (vinyl alcohol)	9002-89-5	≤6.0wt%
8	Zirconium oxide C (T4E-010OP)	Zirconium Oxide (ZrO2)	1314-23-4	79.0-89.0wt%
9		Erbium Oxide	12061-16-4	10.0-14.0wt%
10		Poly (vinyl alcohol)	9002-89-5	≤6.0wt%
11	Zirconium oxide D (T4Y-010EP)	Zirconium Oxide (ZrO2)	1314-23-4	84.0-94.0wt%
12		Yttrium oxide (Y2O3)	1314-36-9	6.0-9.0wt%
13		Manganese oxide	1344-43-0	≤0.03wt%
14		Poly (vinyl alcohol)	9002-89-5	≤6.0wt%

The MSDS of the raw materials can be found in the eCopy #006, 007, 008, and 009.

Combination ratio of Raw materials of the Device

Single-Layer Block

No	Color	Raw Material	Combination ratio(%)
1	A0(White)	Zirconium oxide A	100%
2	A1	Zirconium oxide A	68.39%
		Zirconium oxide B	30.00%
		Zirconium oxide C	1.61%
3	A2	Zirconium oxide A	57.85%
		Zirconium oxide B	40.00%
		Zirconium oxide C	2.15%
4	A3	Zirconium oxide A	53.44%
		Zirconium oxide B	43.33%
		Zirconium oxide C	3.23%
5	A3.5	Zirconium oxide A	29.03%
		Zirconium oxide B	66.67%
		Zirconium oxide C	4.30%
6	A4	Zirconium oxide A	7.96%
		Zirconium oxide B	80.00%
		Zirconium oxide C	5.38%
		Zirconium oxide D	6.67%
7	B1	Zirconium oxide A	68.92%
		Zirconium oxide B	30.00%
		Zirconium oxide C	1.08%
8	B2	Zirconium oxide A	65.06%
		Zirconium oxide B	33.33%
		Zirconium oxide C	1.61%
9	B3	Zirconium oxide A	53.18%
		Zirconium oxide B	43.33%
		Zirconium oxide C	2.15%
		Zirconium oxide D	1.33%
10	B4	Zirconium oxide A	32.80%
		Zirconium oxide B	66.67%
		Zirconium oxide C	0.53%
11	C1	Zirconium oxide A	62.26%
		Zirconium oxide B	30.00%
		Zirconium oxide C	1.08%
		Zirconium oxide D	6.66%
12	C2	Zirconium oxide A	45.05%
		Zirconium oxide B	46.67%
		Zirconium oxide C	1.61%
		Zirconium oxide D	6.67%
13	C3	Zirconium oxide A	30.00%

		Zirconium oxide B	60.00%
		Zirconium oxide D	10.00%
14	C4	Zirconium oxide A	5.59%
		Zirconium oxide B	80.00%
		Zirconium oxide C	1.08%
		Zirconium oxide D	13.33%
15	D2	Zirconium oxide A	31.18%
		Zirconium oxide B	60.00%
		Zirconium oxide C	2.15%
		Zirconium oxide D	6.67%
16	D3	Zirconium oxide A	28.65%
		Zirconium oxide B	66.67%
		Zirconium oxide C	2.68%
		Zirconium oxide D	2.00%
17	D4	Zirconium oxide A	40.00%
		Zirconium oxide B	56.67%
		Zirconium oxide D	3.33%

Multi-Layer Block

No	Color	Raw Material	Combination ratio (%)
1	37 models besides UML512A1-WR	Zirconium oxide A	61.8%
		Zirconium oxide B	36.0%
		Zirconium oxide C	2.2%
2	72 models besides UML512A2-WR	Zirconium oxide A	49.7%
		Zirconium oxide B	46.0%
		Zirconium oxide C	3.0%
		Zirconium oxide D	1.3%
3	72 models besides UML512A3-WR	Zirconium oxide A	43.4%
		Zirconium oxide B	52.0%
		Zirconium oxide C	3.3%
		Zirconium oxide D	1.3%
4	27 models besides AML512M1-WR	Zirconium oxide A	87.4%
		Zirconium oxide B	12.0%
		Zirconium oxide C	0.6%
5	27 models besides AML512M2-WR	Zirconium oxide A	81.0%
		Zirconium oxide B	18.0%
		Zirconium oxide C	1.0%
6	27 models besides AML512M3-WR	Zirconium oxide A	78.9%
		Zirconium oxide B	20.0%
		Zirconium oxide C	1.1%
7	27 models besides UML512B1-WR	Zirconium oxide A	80.6%
		Zirconium oxide B	18.7%

		Zirconium oxide C	0.7%
8	27 models besides UML512B2-WR	Zirconium oxide A	71.2%
		Zirconium oxide B	27.3%
		Zirconium oxide C	1.2%
		Zirconium oxide D	0.3%
9	27 models besides UML512B3-WR	Zirconium oxide A	68.1%
		Zirconium oxide B	30.0%
		Zirconium oxide C	1.4%
		Zirconium oxide D	0.5%
10	27 models besides UML512B4-WR	Zirconium oxide A	64.0%
		Zirconium oxide B	34.7%
		Zirconium oxide C	1.0%
		Zirconium oxide D	0.3%
11	27 models besides UML512C1-WR	Zirconium oxide A	62.9%
		Zirconium oxide B	30.7%
		Zirconium oxide C	1.1%
		Zirconium oxide D	5.3%
12	27 models besides UML512C2-WR	Zirconium oxide A	56.5%
		Zirconium oxide B	36.6%
		Zirconium oxide C	0.9%
		Zirconium oxide D	6.0%
13	27 models besides UML512C3-WR	Zirconium oxide A	61.0%
		Zirconium oxide B	33.4%
		Zirconium oxide C	0.3%
		Zirconium oxide D	5.3%
14	27 models besides UML512C4-WR	Zirconium oxide A	48.6%
		Zirconium oxide B	43.3%
		Zirconium oxide C	0.8%
		Zirconium oxide D	7.3%
15	27 models besides UML512D2-WR	Zirconium oxide A	44.5%
		Zirconium oxide B	49.3%
		Zirconium oxide C	1.8%
		Zirconium oxide D	4.4%
16	27 models besides UML512D3-WR	Zirconium oxide A	43.9%
		Zirconium oxide B	50.7%
		Zirconium oxide C	1.9%
		Zirconium oxide D	3.5%
17	27 models besides UML512D4-WR	Zirconium oxide A	45.7%
		Zirconium oxide B	50.0%
		Zirconium oxide C	1.5%
		Zirconium oxide D	2.8%

※ The color used in the layer composition is calculated by the ratio of each layer and the

content of the summed up raw materials is shown.

Multi-Layer Block Structure and Color

No	model name	Number of Layer	layer composition	Combination ratio	Note (Concept diagram)
1	37 models besides UML512A1-WR	5	A0	20%	
			A1	20%	
			A2	20%	
			A3	20%	
			A35	20%	
2	72 models besides UML512A2-WR	5	A0	20%	
			A2	20%	
			A3	20%	
			A35	20%	
			A4	20%	
3	72 models besides UML512A3-WR	5	A1	20%	
			A2	20%	
			A3	20%	
			A35	20%	
			A4	20%	
4	27 models besides AML512M1-WR	5	A0	20%	**5-layer**
			A0	20%	**4-layer**
			A0	20%	**3-layer**
			A1	20%	**2-layer**
			A1	20%	**1-layer**
5	27 models besides AML512M2-WR	5	A0	20%	
			A0	20%	
			A1	20%	
			A1	20%	
			A1	20%	
6	27 models besides AML512M3-WR	5	A0	20%	
			A0	20%	
			A1	20%	
			A1	20%	
			A2	20%	
7	27 models besides UML512B1-WR	5	A0	20%	
			A0	20%	
			B1	20%	
			B1	20%	
			B2	20%	
8	27 models besides UML512B2-WR	5	A0	20%	
			B1	20%	

			B1	20%	
			B2	20%	
			B3	20%	
9	27 models besides UML512B3-WR	5	A0	20%	
			B1	20%	
			B2	20%	
			B3	20%	
			B3	20%	
10	27 models besides UML512B4-WR	5	A0	20%	
			B1	20%	
			B2	20%	
			B3	20%	
			B4	20%	
11	27 models besides UML512C1-WR	5	A0	20%	
			C1	20%	
			C1	20%	
			C2	20%	
			C2	20%	
12	27 models besides UML512C2-WR	5	A0	20%	
			C1	20%	
			C2	20%	
			C2	20%	
			C3	20%	
13	27 models besides UML512C3-WR	5	A0	20%	
			C1	20%	
			C2	20%	
			C3	20%	
			C3	20%	
14	27 models besides UML512C4-WR	5	A0	20%	
			C1	20%	
			C2	20%	
			C3	20%	
			C4	20%	
15	27 models besides UML512D2-WR	5	A0	20%	
			D2	20%	
			D2	20%	
			D2	20%	
			D3	20%	
16	27 models besides UML512D3-WR	5	A0	20%	
			D2	20%	
			D2	20%	
			D3	20%	

			D3	20%	
17	27 models besides UML512D4-WR	5	A0	20%	
			D2	20%	
			D3	20%	
			D3	20%	
			D4	20%	

※ The colors used for the layer composition are the same as the 17 colors indicated on the raw material solid block.

Summaries of Technological Characteristics & Substantial Equivalence Discussion

	Subject Device	Primary Predicate
Company	ARUMDENTISTRY Co., Ltd.	ARUMDENTISTRY Co., Ltd.
Device Name	ARENA Star, Galaxy Star	Non-Sterile Zirconia Block
510(k) Number	NA	K223253
Model Name	ARENA Star, Galaxy Star	ARENA Star, MontBlanc
Device Classification	POWDER, PORCELAIN/ Porcelain Powder For Clinical Use	POWDER, PORCELAIN/ Porcelain Powder For Clinical Use
Product Code	EIH	EIH
Regulation Number	21 CFR 872.6660	21 CFR 872.6660
Indications for Use	Non-Sterile Zirconia Block (Model name: ARENA Star, Galaxy Star) 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: ARENA Star, MontBlanc) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.
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
Feature	Colored	Colored
Shape	Discs	Discs
Thickness	10, 12, 14, 16, 18, 20, 22, 25, 28, 30	10, 12, 14, 16, 18, 20, 22, 25, 28, 30
Sterility	Non-sterile	Non-sterile
Chemical Composition	ZrO2 with others	ZrO2 with others
Density (post Comment 3sintering)	6.00g/cm 3	6.00g/cm 3
Flexural Strength	>800 MPa per ISO 6872:2015 Type II Class 5	>800 MPa per ISO 6872:2015 Type II Class 5
Sintering temperature	1500 ± 50 ℃	1500 ± 50 ℃
Shade(s)	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4
Contact Level	Surface device with permanent contact	Surface device with permanent contact
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements

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 addition of shades. The chemical composition of both devices is same. In addition, shade colors of the subject device are added. However, it doesn't affect the product's fundamental scientific functionality. Therefore, both devices are substantial equivalent.

Non-Clinical Performance Data

Non-clinical testing data submitted, referenced or relied on in this submission support demonstrating substantial equivalence.

Performance Bench Testing

The proposed device was tested and conforms to:

- Performance tests including Visual, Dimensions, Packaging, Uniformity, Extraneous materials, Chemical Solubility, Flexural Strength, Linear Thermal Expansion, Flexural Strength in accordance with ISO 6872
- Cytotoxicity per ISO 10993-5:2009;
- Intracutaneous Reactivity Test per ISO 10993-10:2010;
- Sensitization Test per ISO 10993-10:2010;
- Acute Systematic Toxicity per ISO 10993-11:2017.

Biocompatibility

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.

Conclusion

Overall, the technological characteristics of the subject device are highly similar to the predicate device. 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 data included in this premarket notification demonstrate substantial equivalence to the Predicate device listed above. The mechanical properties were found to be substantially equivalent to the predicate devices as a result.