October 24, 2024

Argen Corporation
℅ Patsy Trisler
Owner/Regulatory Consultant
Trisler Consulting (dba)
306 Turnberry Ct
Lebanon, Indiana 46052

Re: K242458
Trade/Device Name: ArgenZ MTZ
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 19, 2024
Received: August 19, 2024

Dear Patsy Trisler:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242458

Device Name

ArgenZ MTZ

Indications for Use *(Describe)*

ArgenZ MTZ zirconia can be used for the production of full-contour and substructure restorations up to and including a full arch.
All blanks are processed by 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Number:	K242458
SUBMITTER Name:	The Argen Corporation
Address:	5855 Oberlin Drive San Diego, CA 92121-3706
Contact Person: **Phone:**	Paul Cascone 858.455.7900
Date Prepared:	October 17, 2024
DEVICE Trade Name:	ArgenZ MTZ
Common Name:	Dental Zirconia Ceramics
Classification Name **Number** **Product Code** **Regulatory Class**	Porcelain powder for clinical use 21 CFR 872.6660 EIH 2
Review Panel	Dental
PRIMARY PREDICATE: **REFERENCE DEVICES:**	K222626, Dental Zirconia Ceramic, Aidite (Qinhuangdao) Technology Co., Ltd K150919, ArgenZ Esthetic Plus, The Argen Corporation K190079, ArgenZ HT+, The Argen Corporation
DEVICE DESCRIPTION	The ArgenZ MTZ (referring to multi-translucent, multi-layer) zirconia consist of yttria-stabilized pre-shaded 4 mole and 5 mole percent zirconia. They are manufactured (pressed and sintered) into disc forms and offered multiple thicknesses and multiple shades. They contain oxides of Hafnium and Aluminum and minute amounts of coloring oxides of iron, erbium, cobalt and manganese. The discs are single use, non-sterile devices and used for fabricating dental restorations, using CAD/CAM systems that can accommodate the disc sizes.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The zirconia material complies with ISO 6872:2015 as a type II, meeting the requirements for a class 5 material, with: • flexural strength above 800 MPa and • chemical solubility of less than 100 µg/cm². The physical device is a disc with thicknesses that vary from 10 mm to 30mm. Within a given thickness the top layer is made of 5 Y Zirconia, the bottom layer from 4 Y zirconia with the intervening layers different combinations of 5Y and 4Y. The color intensity increases going from incisal to dentine and the yttria content decreases from incisal to dentine.

INDICATIONS FOR USE STATEMENT	ArgenZ MTZ zirconia can be used for the production of full-contour and substructure restorations up to and including a full arch. All blanks are processed by dental laboratories or by dental professionals.

SAFETY TESTING	The device's biocompatibility was evaluated according to ISO 10993, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system*. According to the Biological Risk Assessment, Cytotoxicity testing (per ISO 10993-5:2009) was conducted.
PERFORMANCE TESTING	Bench testing, performed according to *ISO 6872:2015 Dentistry – Ceramic materials,* showed the ArgenZ MTZ meets the requirements specified in the standard. The test measurements are in the SE table below. In vivo Animal and Human Clinical performance testing were not provided for this submission.
COMPARISON TO THE PREDICATE DEVICE and SUBSTANTIAL EQUIVALENCE CONCLUSION	The information and data provided in this 510(k) establish that the ArgenZ MTZ zirconia device is substantially equivalent to the Aidite primary predicate device's Multilayer 3D-pro model in the intended use, design, principle of operation, and technology including the use of the same zirconia materials. Further ArgenZ MTZ's material is a combination of the two reference devices, Argen's K150919 (consisting of 5 mole percent zirconium) and K190079 (consisting of 4 mole percent zirconium); and ArgenZ MTZ is manufactured using the same processes. The differences in the Indications for Use statement between ArgenZ MTZ and the primary predicate does not change the Intended Use – both are zirconia blanks for use in making dental restorations with CAD/CAM technologies. For complete presentation of the similarities and differences, see the following SE Comparison table.

Substantial Equivalence Comparison Table

Comparison item	Proposed Device (K242458)	Predicate Device (K222626)	Comment
Manufacturer	The Argen Corporation	Aidite (Qinhuangdao) Technology Co., Ltd.	None
Product Name	ArgenZ MTZ	Dental Zirconia Ceramic	None
Product Code	EIH	EIH	Same
Regulation Number	21 CFR § 872.6660	21 CFR § 872.6660	Same
Classification	Class II	Class II	Same
Prescription Use	Yes	Yes	Same
Indications for Use	ArgenZ MTZ zirconia can be used for the production of full-contour and substructure restorations up to and including a full arch. All blanks are processed by dental laboratories or by dental professionals.	Dental Zirconia Ceramic are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.	Same Intended Use Similar Indications
Class (per ISO 6872: 2015)	Class 5	Class 5: Multilayer-3D pro	Same
Composition	Based on yttria-stabilized zirconia 5Y zirconia on top of 4Y zirconia	Based on yttria-stabilized zirconia 5Y zirconia on top of 4Y zirconia	Same
Color	Color	Color	Similar
Intended User	Professional dental technicians	Professional dental technicians	Same
Single Use	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Physical Properties	Conform to ISO 6872:2015	Conform to ISO 6872:2015	Same
Uniformity	Uniform	Uniform	Same
Freedom from extraneous materials	Free from extraneous materials	Free from extraneous materials	Same
Radioactivity	≤ 1.0 $Bq \cdot g^{-1}$	≤ 1.0 $Bq \cdot g^{-1}$	Same
Flexural strength	≥ 800 MPa	Multilayer-3Dpro: ≥ 800 MPa	Similar
Chemical solubility	< 100 $\mu g/cm^2$	< 100 $\mu g/cm^2$	Same
Linear thermal expansion coefficient	$(9.9)\times10^{-6}\ K^{-1}$	Multilayer-3D pro: $(10.4\pm0.5)\times10^{-6}\ K^{-1}$	Similar
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 7405:2018	Similar
Labeling	Complies with 21 CFR 801	Complies with 21 CFR 801	Same