The Argen Corporation
Craig Jolicoeur
Quality & Regulatory Manager
5855 Oberlin Drive
San Diego, California 92121

February 8, 2019

Re: K182833
Trade/Device Name: Argen Z Liquids (ArgenZ Liquid Shade, ArgenZ Incisal Effect, ArgenZ Pontic Reducer, and ArgenZ Color Modifier)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 16, 2018
Received: November 16, 2018

Dear Craig Jolicoeur:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.02.08 10:01:37 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K182833

Device Name
ArgenZ Liquids (ArgenZ Liquid Shade, ArgenZ Incisal Effect, ArgenZ Pontic Reducer, and ArgenZ Color Modifier)

Indications for Use *(Describe)*
ArgenZ Liquids are intended to be used by trained dental technicians as an accessory for shading ArgenZ frameworks and ArgenZ all-zirconia, monolithic restorations for anterior and posterior dental prosthetics.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K182833

510(k) Summary

Submitted by: The Argen Corporation
5855 Oberlin Drive, San Diego, CA 92121
(858) 455-7900 x471 (Phone), (858) 626-8655 (FAX)

Contact person: Craig Jolicoeur

Date prepared: 9/28/2018

Trade name: ArgenZ Liquid Shade, ArgenZ Incisal Effect, ArgenZ Color Modifier, ArgenZ Pontic Reducer
Common name: ArgenZ Liquids
Classification name: Porcelain powder for clinical use (21 CFR 872.6660)
Classification: Class II
Product Code: EIH

Legally marketed devices for which our organization is claiming substantial equivalence:

510(k) Number	Trade Name	Manufacturer
K111257	HEISENBERG DYEING LIQUIDS	3M ESPE AG

Device Description:
ArgenZ Zirconia Coloring Liquids are dilute aqueous solutions of transition and lanthanoid metal salts used in combination with ArgenZ Zirconia material (K071410 and K150919) to properly shade teeth. Elements, which may include (but are not limited to) Co, Cr, Er, Fe, Mn, Pr, Ni, Bi, and Nd are combined with water to result in the finished product.

Intended Use:
ArgenZ Liquids are intended to be used by trained dental technicians as an accessory for shading ArgenZ frameworks and ArgenZ all-zirconia, monolithic restorations for anterior and posterior dental prosthetics.

Predicate devices:
K111257

Performance Data:

The raw materials and manufacturing process used in the fabrication of ArgenZ Liquids are similar to the materials and processes used in the industry to fabricate the predicate device. Section 18 contains test records of parent materials and representative accessories infused into the parent materials. The results demonstrate compliance with the product standard of the parent material.

Performance Data Summary:

Summary of mechanical properties to the product standard (BS EN ISO 6872:2015)

Product	Flexural strength [MPa] from standard minimum value for mean	Test Result
ArgenZ HT+	800	1230
ArgenZ HT+ Shaded with ArgenZ HT Liquid (A4)	800	1223
ArgenZ Anterior	500	868
ArgenZ Anterior Shaded with ArgenZ ST Liquid (A3)	500	765
ArgenZ Anterior Shaded with ArgenZ ST Liquid (C4)	500	963

Summary of chemical properties to the product standard (BS EN ISO 6872:2015)

Product	Chemical solubility [$\mu g/cm^2$]	Test Result
ArgenZ HT+	<100	4.16
ArgenZ HT+ Shaded with ArgenZ HT Liquid (A4)	<100	4.16
ArgenZ Anterior	<100	20.80
ArgenZ Anterior Shaded with ArgenZ ST Liquid (A3)	<100	10.32
ArgenZ Anterior Shaded with ArgenZ ST Liquid (C4)	<100	8.30

Predicate Device Comparison (Liquid):

	ArgenZ Liquids	HEISENBERG DYEING LIQUIDS
Properties and Information		
510(k)	N/A	K111257
Indications for Use	ArgenZ Liquids are intended to be used by trained dental technicians as an accessory for shading ArgenZ frameworks and ArgenZ all-zirconia, monolithic restorations for anterior and posterior dental prosthetics.	Liquid ceramic aid for complete or partial coloring of all zirconium oxide blanks intended to be used for all ceramic dental restorations
Prescription Use	Prescription Only	Prescription Only
Target Population	General, mostly adults	General, mostly adults
Type of Packaging	Liquid container	Liquid container
Method of Manufacturer	Batch, at VITA shade	Batch, at VITA shade
Packaging Volume (mL)	30 and 100	100 and 250
VITA Shade	16	16
Items in Product Line	~ 90	~50
Storage Conditions	2 years @ 25-75°C	3-4 years at 4-10°C
General Physical Form	Liquid	Liquid
Specific Physical Form	Liquid	Liquid

Odor	Characteristic odor	Characteristic odor
Color	Yellow/orange	Yellow/orange
pH	6.5-7.5	6.5-7.5
Boiling Point	100°C	100°C
Specific Gravity	1.0-1.10 g/cm^3	1.00-1.10 g/cm^3
Solubility in Water	100%	100%
Sterility	Non-sterile	Non-sterile

Summary of the biological testing conducted on the device:

The device was evaluated for cytotoxicity based on ISO 10993-5 (Section 8.2) using the *Minimal Essential Media (MEM) Elution Test*. According to the criteria described in Table 1 (Section 8.5), a reactivity grade of greater than 2 (mild reactivity) is considered a cytotoxic effect.

Test Requirements & Rationale for Cytotoxicity

Test articles for the cytotoxicity testing were selected as representative samples for each product family, and determined to be worst case scenarios for potential biocompatibility issues. Specified zirconia materials will be used as a medium for testing the products.

Table 1, shows the rationale used to determine which sample set would represent the entire product category. Since direct testing using the overlay method will be employed to determine cytotoxicity of the samples, indirect testing will not be necessary.

Table 1: Rationale for liquid sample selection

Liquids Type	Shade	Elements Present			Rationale
ST on K150919	A3	Er	Fe	Ni	Highest Er
ST on K150919	C4	Mn	Fe	Ni	Mn presence, highest presence of Ni
HT on K071410	A4	Cr	Fe		Highest concentration of elements
HT on K071410	B4	Pr	Fe	Cr	Pr presence, Cr presence

All tests articles showed no evidence of causing any cell lysis or toxicity. All test articles met the requirements of the test since the grade was less than or equal to grade 2 (mild reactivity).

Complete test reports are available in Section 15 of this submission.

Conclusion: Due to the lack of response, the products are considered biocompatible and substantially equivalent to the predicate devices.

In addition, strong evidence supporting biocompatibility of the material can be seen when comparing chemical solubility results from the white and shaded materials.

Conclusion:

The proposed and predicate devices are composed of a similar material makeup.
All devices have similar indications for use.
The proposed and predicate devices have similar properties.
The performance results and technical characteristics support the findings of substantial equivalence.
We are claiming substantial equivalence of the ArgenZ Liquids to the predicate device.