DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 13, 2015

The Argen Corporation
Mr. Craig Jolicoeur
Quality & Regulatory Manager
5855 Oberlin Drive
San Diego, CA 92121-4718

Re: K150919
Trade/Device Name: ArgenZ Esthetic Plus
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: March 27, 2015
Received: April 17, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

Alloy Makers To The World
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Indications for Use Statement

510(k) Number (if known): K150919

Device Name: ArgenZ Esthetic Plus

Indications For Use: ArgenZ Esthetic Plus blanks are intended to be used in the fabrication of inlays, crowns, copings, and fixed bridges (up to 3 units) using various CAD/CAM systems.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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510(k) Summary

Submitted by: The Argen Corporation
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Contact person: Craig Jolicoeur

Date prepared: 3/27/2015

Trade name: ArgenZ Esthetic Plus
Common name: Dental Ceramic
Classification name: Porcelain powder for clinical use (21 CFR 872.6660)
Classification: Class II
Product Code: EIH

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

510(k) Number	Trade Name	Manufacturer
K143330	BruxZir Anterior	PRISMATIK DENTALCRAFT, INC.

Device Description:
ArgenZ Esthetic Plus is a pressed Yttria stabilized Zirconia with oxides of Hafnium and Aluminum and an organic binder.
ArgenZ Esthetic Plus satisfies requirements for Class 5 (type II) ceramics when tested according to ISO 6872:2008.

Intended Use:
ArgenZ Esthetic Plus blanks are intended to be used in the fabrication of inlays, crowns, copings, and fixed bridges (up to 3 units) using various CAD/CAM systems.

Predicate device:
K143330

Summary of the physical testing conducted on the device:
The materials are identical to the predicate device and hence have the same physical properties. The properties satisfy requirements for a Class 5 (type II) ceramic when tested in accordance with ISO 6872:2008. A comparison to the predicate device is below:

Comparison between Predicate and Proposed Device

	Predicate Devices	**Proposed Device**
	BruxZir™ Anterior (K143330)	**Argen Z Esthetic Plus**
Classification of Ceramic	Type II, Class 6	Same
Shapes/Sizes	Standard, R, Z, Type, DD, ZZ, ZZ Notch	100/98/95mm Dia x 10/14/18/22/25mm High
Material	Tosoh Powder	Same
Flexural Strength	Meets requirements, per ISO 6872	>600 MPa Mean Value
Coefficient of Thermal Expansion (CTE) / (25-500 ºC)	11 X 10^{-6}/K	Same
Density	6.05 g/cm^3	Same
Biocompatibility	Biocompatible	Same
Indications for Use	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior location.	ArgenZ Esthetic Plus blanks are intended to be used in the fabrication of inlays, crowns, copings, and fixed bridges (up to 3 units) using various CAD/CAM systems.

We can conclude that ArgenZ Esthetic Plus have comparable technical characteristics and Indications for Use to the predicate device.

Summary of the non-clinical testing:
Non-clinical test data was used to support the claim of substantial equivalency. The flexural strength, fracture toughness, hardness, and translucency ensure conformance of ArgenZ Esthetic Plus to the input requirements and the flexural strength requirements of ISO 6872:2008.

Conclusion from the non-clinical testing:
The proposed device, ArgenZ Esthetic Plus, is the same material as the predicate device. It has the same performance specifications and intended use as the predicate device - BruxZir Anterior (K143330). There are no changes to the device, so no additional risks are present to the safety and efficacy.
Since the device is made from the same material, and has the same intended use as the predicate device. A conclusion can be drawn that the proposed device is substantially equivalent to the predicate device.

Summary of the biological testing conducted on the device:
The materials (Yttrium-stabilized Zirconia) used to produce ArgenZ Esthetic Plus have been studied extensively in medical applications. This type of material is the standard used for most all ceramic dental restorations in the world.
Since the material used to produce the blanks is identical to the material used to produce the predicate device (see table on previous page), it follows that the proposed product is biocompatible.

Substantial equivalence/Conclusion:
The proposed and predicate device is composed of a pressed Yttria stabilized Zirconia with oxides of Hafnium and Aluminum and an organic binder.
Both the proposed and predicate devices have identical chemical compositions. Also, the physical and biological properties of the predicate and proposed devices are the same. In addition, both have the same intended use. ArgenZ Esthetic Plus is substantially equivalent in safety and effectiveness to the predicate device.
We are claiming substantial equivalence of the ArgenZ Esthetic Plus to the predicate device.