Alloy Makers To The World
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510(k) Summary
K190079

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Trade name: ArgenZ HT+
Common name: ArgenZ
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
K180252	Primary Predicate Device	Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank	Crown Porcelain Dental Technology Co., Ltd.
K071410	Reference Device	Argen Pearl Brand Zirconia	The Argen Corporation

Device Description:
ArgenZ HT+ is a pressed Yttria stabilized Zirconia with primary oxides of Hafnium and Aluminum with naturally occurring trace oxides used to produce various shades.

Intended Use:
ArgenZ HT+ (high translucent plus) zirconia can be used for the production of full contour and substructure restorations up to a full arch.

Performance Data:

The raw materials and manufacturing process used in the fabrication of ArgenZ HT+ are similar to the materials and processes used in the industry to fabricate the predicate devices.
Both materials fall into the same product classification (Class 5) per ISO 6872. Both have stated similar intended uses, chemical compositions, and physical properties.
The results demonstrate compliance with the product standard and support our claim for substantial equivalence.

Performance Data Summary:

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

Product	**Flexural strength [MPa] from standard minimum value for mean**	**Test Result**
ArgenZ HT+	800	1348
ArgenZ HT+ Shade (A4)	800	1172
ArgenZ HT+ Shade (OM1)	800	1143
Argen Pearl Brand Zirconia	800	900

Product	**Coefficient of Thermal Expansion**	**Test Result µm/m-C°**
ArgenZ HT+	25-500°C	10.3
Argen Pearl Brand Zirconia	0-800°C	9

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

Product	**Chemical solubility [µg/cm²]**	**Test Result**
ArgenZ HT+	<100	66.11
ArgenZ HT+ Shade (A4)	<100	3.10
ArgenZ HT+ Shade (OM1)	<100	3.10

Predicate Device Comparison:

ITEM	Subject Device ArgenZ HT+	Predicate Device K180252
Product Code	EIH	EIH
Regulation Number	872.6660	872.6660

Intended Use	ArgenZ HT+ (high translucent plus) zirconia can be used for the production of full contour and substructure restorations up to a full arch. Note: The predicate device states an intended use that is specific to the manufactures business. Both materials can be used for the applications stated by the predicate. Both meet Class 5 mechanical and chemical property requirements of ISO 6872. We recommend the aforementioned Intended use.	Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.
Feature	Shaded	Colored
Shape	Discs	Discs
Type and Class per ISO 6872: 2015	Type II Class 5	Type II Class 5
Sterility	Non-sterile	Non-sterile
Chemical Composition (Weight %)	ZrO2+HfO2+Y2O3 > 99 wt% Inorganic Pigments < 1%	ZrO_2 >99.0% Inorganic Pigment (Al_2O_3, SiO_2, Fe_2O_3 , Er_2O_3) < 1%
Crystal Morphology	Tetragonal	Tetragonal
Density	6.08g/cm^3	6.00g/cm^3
Sintering temperature	1500℃	1500±50℃
Performance	Comply with ISO 6872	Comply with ISO 6872
Contact Level	surface device with permanent contact (>30 days)	surface device with permanent contact (>30 days)
Biocompatibility	Tested for Cytotoxicity on shaded material, no adverse reactions identified.	Tested for Cytotoxicity, irritation, sensitization, accurate systematic toxicity, genotoxicity, no adverse react identified.

Summary of the biological testing conducted on the device:

The device was evaluated for cytotoxicity based on ISO 10993-5 using the *ISO Agarose Overlay Method*.

Test Results/Summary:

The test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test.

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 ArgenZ HT+ to the predicate device.