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

September 16, 2015

The Argen Corporation
c/o Ms. Maria Rao
Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, MA 02703

Re: K143051
Trade/Device Name: ArgenIS Titanium Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 13, 2015
Received: August 17, 2015

Dear Ms. Rao:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

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 Radiological Health

Enclosure

510(k) Number (if known): K143051

Device Name: **ArgenIS Titanium Abutments**

Indications for Use:

ArgenIS patient specific abutments are intended to be single use available by prescription only to dental professionals (dental technicians and Dentists) in the construction of dental restorations supported by endosseous dental implants. The Argen Is Abutment is designed to specifically fit an individual patients needs in order to more naturally support the tissue, esthetics, and function of the final restoration.

The ArgenIS titanium abutments are compatible with the following implant systems:

Implant Brand and Type	Implant Diameter
Nobel Biocare Replace Select	3.5mm
Nobel Biocare Replace Select	4.3mm
Nobel Biocare Replace Select	5.0mm
Biomet 3i Certain	3.25mm
Biomet 3i Certain	4.0mm
Biomet 3i Certain	5.0mm
Straumann Tissue Level - RN	3.3mm
Straumann Tissue Level - RN	4.1mm
Straumann Tissue Level - RN	4.8mm
Zimmer Tapered Screw-Vent	3.7mm
Zimmer Tapered Screw-Vent	4.1mm
Zimmer Tapered Screw-Vent	4.7mm
Zimmer Tapered Screw-Vent	6.0mm

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subparts D) (21 CFR 807 Subpart D)

510(k) Summary

Sponsor: The Argen Corporation
5855 Oberlin Drive
San Diego, CA 92121

Contact: Maria Rao, Regulatory Consultant
Phone: 401-871-3489

Date: September 16, 2015

Trade Name: ArgenIS Titanium Abutments

Common Name: Implant Abutment

Classification Name: Endosseous Dental Implant Abutment

Classification: 872.3630, Class II

Product Code: NHA

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):

Primary Predicate

Trade Name:	Nobel Biocare Replace Select
510(k) Number:	K062566
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 2

Trade Name:	Biomet 3i Certain
510(k) Number:	K130949
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 3

Trade Name:	Straumann SynOcta
510(k) Number:	K081419
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 4

Trade Name:	Zimmer Tapered Screw-Vent
510(k) Number:	K133339
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 5

Trade Name:	Inclusive Titanium Abutment Blanks
510(k) Number:	K083192
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Dental Implant Abutment

Predicate Device No. 6

Trade Name:	SFI Bar® Implant Abutments for 7 Platforms
510(k) Number:	K130183
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Dental Implant Abutment

Predicate Device No. 7

Trade Name:	SFI Bar® Implant Abutments for 9 Platforms
510(k) Number:	K132814
Regulation Number:	872.3630
Classification Code:	NHA
Device Classification Name:	Endosseous Dental Implant Abutment

Description of Device:

Argen IS Abutments are designed specifically for an Individual patient and then milled from a Titanium blank with a pre-milled interface correlating to a specific implant system. This abutment can be fixed in the laboratory model work containing the implant analog for final construction of the related prosthetic restoration. The Argen IS Abutment is then intended to be fixed in the mouth with the included prosthetic screw. The Argen IS Abutment is supplied with 2 screws (1) A Final Screw for fixing to the endosseuos Implant. (2) A lab screw for Laboratory use during construction of related restoration to avoid any damage to the final prosthetic screw. The final prosthetic screw will be marked “final Screw”. The final screw must be torqued on the endosseuos Implant with the specific torque setting provided. The device is finalized at the Argen facility and provided to the dental laboratory in a final patient-specific form.

Minimum and Maximum Gingival Height is 0-6mm
Minimum diameter at abutment/implant interface is 3.5mm to interface base
Maximum length of abutment from abutment/implant interface is 12.5mm
Minimum length of abutment post (length above the abutment collar/gingival height) is 4.0mm
Minimum wall thickness at abutment/implant interface is 0.65mm
Maximal angle in relationship to the long axis of implant is 30°

The proposed ArgenIS Titanium Abutments are available in a range of diameters and connection type.

The available range of diameters and connection type is summarized below:

IMPLANT BRAND NAME	PLATFORM CONNECTION	CYLINDER	CONNECTION TYPE
Nobel Biocare Replace Select	3.5mm	17.225 – 17.275MM	Internal Hex
Nobel Biocare Replace Select	4.3mm	17.225 – 17.275MM	Internal Hex
Nobel Biocare Replace Select	5.0mm	17.225 – 17.275MM	Internal Hex
Biome 3i Certain	3.4mm	17.225 – 17.275MM	Internal Hex
Biomet 3i Certain	4.1mm	17.225 – 17.275MM	Internal Hex
Biomet 3i Certain	5.0mm	17.225 – 17.275MM	Internal Hex
Straumann Tissue Level	4.8mm	17.225 – 17.275MM	Internal Hex
Zimmer Tapered Screw-Vent	3.5mm	17.225 – 17.275MM	Internal Hex
Zimmer Tapered Screw-Vent	4.5mm	17.225 – 17.275MM	Internal Hex
Zimmer Tapered Screw-Vent	5.7mm	17.225 – 17.275MM	Internal Hex

Intended Use of the Device:
ArgenIS patient specific abutments are intended to be single use available by prescription only to dental professionals (dental technicians and Dentists) in the construction of dental restorations supported by endosseous dental implants. The Argen Is Abutment is designed to specifically fit an individual patients needs in order to more naturally support the tissue, esthetics, and function of the final restoration.

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Biomet 3i Certain	3.25mm
Biomet 3i Certain	4.0mm
Biomet 3i Certain	5.0mm
Straumann Tissue Level - RN	3.3mm
Straumann Tissue Level - RN	4.1mm
Straumann Tissue Level - RN	4.8mm
Zimmer Tapered Screw-Vent	3.7mm
Zimmer Tapered Screw-Vent	4.1mm
Zimmer Tapered Screw-Vent	4.7mm
Zimmer Tapered Screw-Vent	6.0mm

Technological Characteristics:
The Argen IS Abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles, materials, technology and processes are the same as other Sterngold dental devices previously cleared by FDA.
Substantial Equivalence:

The Argen IS Abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and materials are the same as the predicate devices.
Compatibility and substantial equivalency was determined by comparing the design features including diameters, lengths, materials, implant-to-abutment connection platform and intended use of proposed devices to predicate devices.
Indications for Use and abutment design parameters are the same or similar to the predicate devices.

Any differences between proposed devices and predicate devices do not render the device NSE.

See Substantial Equivalence Comparison table below.

Features	**New Device**	**Primary Predicate**	**Predicate 2**	**Predicate 3**	Predicate 4	**Predicate 5**	**Predicate 6 and 7**
	ArgenIS Titanium Abutment Blanks The Argen Corporation	Nobel Replace Tapered Conical Connection Nobel Biocare K062566	CP4 Osseotite Certain Dental Implants Biomet 3i K130949	Straumann Dental Implant System Straumann K081419	Zimmer Dental Tapered ScrewVent Implants Zimmer Dental K133339	Inclusive Titanium Abutment Blanks Inclusive Dental K083192	SFI Implant Abutments Sterngold Dental K130183 K132814
Material	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy
Prosthetic Connection	Nobel Biocare Replace Select Biomet 3i Certain Straumann SynOcta Zimmer TSV	Nobel Replace Tapered Conical Abutments	Biomet 3i Certain Abutments	Straumann ITI Abutments Straumann SynOcta	Zimmer Tappered Screw-Vent Abutments	Nobel Active Internal NP and RP Straumann Bone Level NC and RC Nobel Branemark RP	Nobel Biocare Branemark Nobel Biocare Replace Biomet 3i Certain Biomet 3i Osseotite Zimmer TSV Straumann SLA Active Astra OsseoSpeed
Indications for Use	See Indications for Use Statement above	Intended to be surgically placed in the bone of upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function.	Intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous patients	Intended for the treatment of oral endosteal implantation in the upper and lower jaw and for functional and esthetic oral rehabilitation of edentulous and partially dentate patients.	Intended for use in the maxilla or mandible for immediate loading or for loading after conventional or delayed healing period.	Intended to be used in conjunction with endosseous implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses.	Intended to be used with dental implants to support and/or retain removable dental prostheses for partially or totally edentulous patients to restore chewing function.
Platform type/diameter, abutment parameters	See Device Description above	Internal Hex; 3.5mm, 4.3, 5.0; 30° angulation	Internal Hex; 3.4mm, 4.1, 5.0; 30° angulation	.Internal Hex; 4.8mm; 30° angulation	Internal Hex; 3.5mm, 4.5, 5.7; 30° angulation	Different compatible implant platforms; 30° angulation	No anti-rotation design; multi-unit systems only
Type of Retention	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.

Performance Data:
Bench testing was conducted to evaluate and determine conformance to performance specifications and functionality according to its intended use.
Testing included tolerance analysis to ensure abutment/implant interface compatibility. Functional fit checks of abutment blank to compatible implant, analog and prosthetic screw. Testing showed correct functionality of the device as per its intended use, including dimensional compatibility, and mechanical performance.

Fatigue testing was conducted on worst case scenario samples. Worst case scenario was defined as the smallest diameter and shortest length from each platform. One (1) implant size from each of the proposed platforms was tested per ISO 14801.

The Argen IS Abutments have the same sterilization process and parameters, and bio-compatibility as previous cleared Sterngold devices. As a result, they are substantial equivalent to its predicates.

Substantial Equivalence
Non-clinical test data was used to support the substantially equivalence claim. The non-clinical testing consisted of tolerance analysis of platforms to ensure implant/abutment compatibility, dimensional verification and implant mating checks. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments."
The summary of technological characteristics, tolerance analysis, and functional testing indicate that the device is substantially equivalent for its intended use and performs as well as the predicate devices.

Conclusion:
Based on the above analysis, technological characteristics and performance testing, the Argen IS Abutments are substantially equivalent in intended use, material, design and performance to its predicate devices.
The Argen IS Abutments do not create any new risks or increased risks compared to the predicate devices. The summary of technological characteristics and performance testing indicate that the device is substantially equivalent to its predicate devices.