DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2016

Argen Corporation
% Ms. Maria Rao
Regulatory Consultant
Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, Massachusetts 02703

Re: K160248
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: June 30, 2016
Received: July 1, 2016

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,

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

510(k) Number (if known): __**K160248**___

Device Name: **ArgenIS Titanium Abutments**

Indications for Use:

ArgenIS Titanium Abutments are intended to be single use available by prescription only in the construction of dental restorations supported by the endosseous dental implant. The ArgenIs Titanium Abutments are designed to specifically fit an individual patient's needs of the final restoration. All digitally designed abutments files are intended to be sent to Argen manufacturer for milling.
The ArgenIS Titanium Abutments are compatible with the following implant systems:

IMPLANT BRAND NAME	PLATFORM	Manufacturer	Implant Trade Name	Implant Line/Connection	Implant Diameter
Nobel Biocare Replace Select	6.0mm	Nobel Biocare USA	Nobel Replace Tapered Conical Connection	Nobel Replace Internal Conical Connection WP	6.0mm
Nobel Biocare Active	3.5mm	Nobel Biocare AB	NobelActive Internal Connection Implant	Nobel Active Internal Conn. RP and NP	3.0, 3.5, 4.3, 5.0mm
Nobel Biocare Active	4.3/5.0mm	Nobel Biocare AB	NobelActive Internal Connection Implant	Nobel Active Internal Conn. RP and NP	3.0, 3.5, 4.3, 5.0mm
Straumann Bone Level	3.3mm	Straumann USA	Straumann Bone Level Tapered Implants	Bone Level Internal Conn. NC	3.3mm
Straumann Bone Level	4.1/4.8mm	Straumann USA	Straumann Bone Level Tapered Implants	Bone Level Internal Conn. RC	4.1, 4.8mm
Straumann Synocta	4.8mm	Institut Straumann AG	Straumann Dental Implant	Synocta Implant Internal Conn. 4.8mm RN (Reg. Neck)	4.8, 6.5mm
Straumann Synocta	6.5mm	Institut Straumann AG	Straumann Dental Implant	Synocta Implant Internal Conn. 6.5mm (Wide Neck)	4.8, 6.5mm
Astra Tech OsseoSpeed	3.5/4.0mm	Astra Tech AB	AstraTech Implant OsseoSpeed	OsseoSpeed Internal Conical Connection RP	3.6, 4.2, 4.8mm
Astra Tech OsseoSpeed	4.5/5.0mm	Astra Tech AB	AstraTech Implant OsseoSpeed Plus	OsseoSpeed Plus Internal Conical Connection RP	3.0, 3.5, 4.0, 4.5, 5.0mm

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

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

2. **Contact:** Paul Cascone
   Senior Vice-President of Research & Development
   Phone: 858-455-7900

3. **Date:** August 3, 2016

4. **Trade Name:** ArgenIS Titanium Abutments

5. **Common Name:** Implant Abutment

6. **Classification Name:** Endosseous Dental Implant Abutment

7. **Classification:** 872.3630, Class II

8. **Product Code:** NHA

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

   9.1 Primary Predicate:
   Trade Name: ArgenIS
   510(k) Number: K143051
   Regulation Number: 872.3630
   Classification Code: NHA
   Device Classification Name: Endosseous Dental Implant Abutment

   9.2 Reference Device No. 2
   Trade Name: Nobel Biocare Replace
   510(k) Number: K022424
   Regulation Number: 872.3640
   Classification Code: DZE
   Device Classification Name: Implant, Endosseous, Root-Form

   9.3 Reference Device No. 3
   Trade Name: Nobel Biocare Active
   510(k) Number: K102436, K071370, K142260
   Regulation Number: 872.3640
   Classification Code: DZE
   Device Classification Name: Implant, Endosseous, Root-Form

9.4 Reference Device No. 4

Trade Name: Straumann Bone Level
510(k) Number: K083550, K121131
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Implant, Endosseous, Root-Form

9.5 Reference Device No. 5

Trade Name: Straumann Dental Implant System
510(k) Number: K033243
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Implant, Endosseous, Root-Form

9.6 Reference Device No. 6

Trade Name: Astra Tech Implants OsseoSpeed
510(k) Number: K024111
Regulation Number: 872.3640
Classification Code: DZE
Device Classification Name: Endosseous Dental Implant Abutment

10.0 Description of Device:

Argen IS Titanium 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 Titanium Abutments are then intended to be fixed in the mouth with the included prosthetic screw. The Argen IS Titanium Abutments are 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 available range of diameters and connection type is summarized on the table below:

11. **Intended Use**

ArgenIS Titanium Abutments are intended to be single use available by prescription only in the construction of dental restorations supported by the endosseous dental implant. The ArgenIs Titanium Abutments are designed to specifically fit an individual patient's needs of the final restoration. All digitally designed abutments files are intended to be sent to Argen manufacturer for milling.

The ArgenIS Titanium Abutments are compatible with the following implant systems:

IMPLANT BRAND NAME	PLATFORM	Manufacturer	Implant Trade Name	Implant Line/Connection	Implant Diameter
Nobel Biocare Replace Select	6.0mm	Nobel Biocare USA	Nobel Replace Tapered Conical Connection	Nobel Replace Internal Conical Connection WP	6.0mm
Nobel Biocare Active	3.5mm	Nobel Biocare AB	NobelActive Internal Connection Implant	Nobel Active Internal Connection RP and NP	3.0, 3.5, 4.3, 5.0mm
Nobel Biocare Active	4.3/5.0mm	Nobel Biocare AB	NobelActive Internal Connection Implant	Nobel Active Internal Connection RP and NP	3.0, 3.5, 4.3, 5.0mm
Straumann Bone Level	3.3mm	Straumann USA	Straumann Bone Level Tapered Implants	Bone Level Internal Connection NC	3.3mm
Straumann Bone Level	4.1/4.8mm	Straumann USA	Straumann Bone Level Tapered Implants	Bone Level Internal Connection RC	4.1, 4.8mm
Straumann Synocta	4.8mm	Institut Straumann AG	Straumann Dental Implant	Synocta Implant Internal Connection 4.8mm RN (Reg. Neck)	4.8, 6.5mm
Straumann Synocta	6.5mm	Institut Straumann AG	Straumann Dental Implant	Synocta Implant Internal Connection 6.5mm (Wide Neck)	4.8, 6.5mm
Astra Tech OsseoSpeed	3.5/4.0mm	Astra Tech U.S.A.	AstraTech Implant OsseoSpeed	OsseoSpeed Internal Conical Connection RP	3.5/4.0mm
Astra Tech OsseoSpeed	4.5/5.0mm	Astra Tech U.S.A.	AstraTech Implant System OsseoSpeed	OsseoSpeed Plus Internal Conical Connection RP	4.5/5.0mm

12. **Technological Characteristics**

The Argen IS Titanium Abutments are substantially equivalent to the currentlmarketed 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.

13. **Substantial Equivalence**

The Argen IS Titanium 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. Minor changes in descriptive terms used in the indications for use do not change the intended use of the proposed device. Any differences between the proposed devices and predicate devices do not render the device NSE.
See Substantial Equivalence Comparison table below.

14. **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 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. The worst case scenarios from each of the proposed platforms were tested per ISO 14801.
The Argen IS Titanium 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. No changes were made that would affect the bio-compatibility and sterilization validation previously conducted.
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.

15. **Conclusion**

Based on the above analysis, technological characteristics and performance testing, the Argen IS Titanium Abutments are substantially equivalent in intended use, material, design and performance to its predicate devices. The Argen IS Titanium 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.

Features	New Device	Primary Predicate	Reference 2	Reference 3	Reference 4	Reference 5	Reference 6
	ArgenIS Titanium Abutments The Argen Corporation	Argen IS Ttanium Abutments K143051 The Argen Corporation	Nobel Replace Tapered Conical Connection Nobel Biocare U.S.A. K022424	Nobel Active Implants Nobel Biocare US.A. K102436, K071370, K142260	Straumann Bone Level K083550, K121131 Straumann USA	Synocta Implants K033243 Straumann USA	Astra Tech Implants OsseoSpeed K024111 Astra Tech
Material	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	CP Titanium	CP Titanium	CP Titanium	CP Titanium	CP Titanium
Prosthetic Connection	Nobel Biocare Replace Select 6.0mm Nobel Biocare Active Straumann Bone Level, Straumann Synocta, Astra Tech OsseoSpeed	Nobel Biocare Replace Select Biomet 3i Certain Straumann SynOcta Zimmer Tapered Screw-Vent	Nobel Replace Tapered Conical Abutments	Nobel Biocare Active	Straumann Bone Level	Straumann SynOcta	Astra OsseoSpeed 3.5/4.0mm and 4.5/5.0mm
Indications for Use	ArgenIS Titanium Abutments are intended to be single use available by prescription only in the construction of dental restorations supported by the endosseuos dental implant. The ArgenIs Titanium abutments are designed to specifically fit an individual patient's needs of final restoration. All digitally designed abutment files are intended to be sent to Argen manufacturer for milling.	ArgenIS patient specific abutments are intended to be single use available by prescription only to dental professionals (dental technicians and Dentists) in the constructions of dental restorations supported by endosseuos dental implants. The Argen IS Abutment is designed to specifically fit an individual pateints needs in order to more naturally support the tissue, esthetics, and functions of the final restoration.	The Replace HA Coated Implant is both for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Replace HA Coated Implant is intended for immediate placement and function on single tooth and/or multiple tooth applications in good quality bone (type I or type I1 bone), to restore chewing function. Multiple tooth applications may be splinted with a bar. .	Intended to be surgically placed in the bone of the 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 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.	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstruction such as crowns or bridges. The ITI synOcta Measo abutments are indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.	Intended for endosseous implantation in the mandible and maxilla supporting single-tooth replacements, partial and total fixed/fixed detachable bridges and overdentures. One or two stage surgical procedure can be used. When using one stage surgical protocol, immediate loading may be applied in the anterior mandibular region if at least four implants are splinted with a bar, or a continuous suprastructure.
Implant Diameters, Lengths	3.3mm , 3.5mm, 4.0mm, 4.1mm, 4.3mm, 4.5mm, 4.8mm, 6.0mm, 6.5mm	3.25mm – 6.0mm	Diameters 3.5mm, 4.3mm, 5.0mm, 6.0mm Lengths 10mm, 13mm, 16mm	Diameters 3.0mm, 3.5mm, 4.3mm, 5.0mm Lengths: 10- 15mm	Diameters 3.3mm, 4.1mm, 4.8mm Lengths 8mm, 10mm, 12mm, 14mm	Diameters 4.8mm, 6.5mm	Diameters 3.5mm, 4.0mm, 4.5 mm, 5.0mm Lengths 8mm, - 19mm,
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.
Manufacturing Process	Machining	Machining	Machining	Machining	Machining	Machining	Machining
Abutment Sterilization	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)	Moist Heat (Steam)
Abutment Angulation	0º - 30º	0º - 30º	0º - 30º	0º - 30º	0º - 25º	0º - 20º	0º - 20º