May 18, 2018

Argen Corporation
c/o Gordon Craig
Regulatory Consultant
Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, Massachusetts 02703

Re: K172430
Trade/Device Name: ArgenIS Titanium Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 9, 2018
Received: April 16, 2018

Dear Gordon Craig:

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.

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.

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,

Andrew I. Steen -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172430

Device Name
ArgenIS Titanium Abutments

Indications for Use *(Describe)*

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
Hiossen ET III SA	3.5mm	Hiossen	Hiossen Implant System	Internal Hex	3.75, 3.77mm
Hiossen ET III SA	4.0/4.5/5.0mm	Hiossen	Hiossen Implant System	Internal Hex	4.25, 4.65, 4.63, 4.6, 5.1, 5.08, 5.05mm
Nobel Active Wide Platform (WP)	5.5mm	Nobel Biocare AB	Nobel Active Wide Platform (WP)	Internal Hex	5.5mm

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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:** May 18, 2018

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):**

   Primary Predicate Device:
   ArgenIS Titanium Abutments – K160248

   Reference Devices:
   Hiossen Implant System – K140934
   Nobel Biocare Nobel Active Wide Platform (WP) – K133731

10. **Description of Device:**
    The ArgenIS 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. The titanium abutment may be designed with a maximum angulation of 30°. The abutment is then fixed with the use of a lab screw to a model containing the implant analog for final construction of the related prosthetic restoration. The ArgenIS Titanium Abutments are then intended to be fixed in the mouth with the prosthetic final screw.
    The ArgenIS Titanium Abutments are supplied with two package configurations. One includes two final screws and the abutment and another includes one final screw and one lab screw and the abutment. The final screw is used for fixing abutment to the endosseous implant body, and the lab screw is used 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 endosseous implant body 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. There are no accessories associated with the subject devices.

Minimum and Maximum Gingival Height is 0.5mm - 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 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°

All digitally designed abutment files are intended to be sent to Argen manufacturer for milling. Argen is a registered contract manufacturer with a quality system under FDA QSR regulation.

11. **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
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Nobel Active Wide Platform (WP)	5.5mm	Nobel Biocare AB	Nobel Active Wide Platform (WP)	Internal Hex	5.5mm

12. **Technological Characteristics**

The Argen IS Titanium Abutments are substantially equivalent to the currently marketed predicate devices. The intended use, fundamental operating principles, materials, technology and processes are the same as other Argen 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. The Indications for Use for the subject device differs from the primary predicate by the list of compatible implant bodies. Implant body 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. Abutment design parameters are similar to the predicate devices and substantial equivalence has been demonstrated through performance testing data. 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	Reference Device	Reference Device
	ArgenIS Titanium Abutments The Argen Corporation	Argen IS Ttanium Abutments K160248 The Argen Corporation	Hiossen Implant System K140934 Hiossen, Inc.	Nobel Biocare Nobel Active Wide Platform (WP) K133731 NobelBiocare AB
Material	Titanium-6AL-4 Vanadium ELI Alloy	Titanium-6AL-4 Vanadium ELI Alloy	CP Titanium	CP Titanium
Prosthetic Connection	Hiossen ET III SA 3.5mm, 4.0/4.5/5.0mm Nobel Biocare 5.5mm	Nobel Biocare Replace 6.0mm Nobel Biocare Active Straumann Bone Level, Straumann Synocta, Astra Tech OsseoSpeed	3.5,3.77mm, 3.75mm, 4.2mm, 4.25mm,4.45mm, 4.6mm, ,4.63mm, 4.65mm,4.9mm,5.0mm,5.05mm,5.08mm, 5.1mm,5.92mm,5.95mm,6.0.6.8mm	Nobel Biocare Active Wide Platform 5.5mm
Indications for Use	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 abutment files are intended to be sent to Argen manufacturer for milling.	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 abutment files are intended to be sent to Argen manufacturer for milling.	Indicated for use in partially or fully edentulous mandibles and maxillae in support of single or multiple unit restorations including cemented retained, screw retained or overdenture, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. ETIII SA Ultra Wide Fixture is intended to be used in the molar region.	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. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or nonsplinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Implant Diameters	Hiossen 3.77, 3.75, 4.25, 4.65, 4.63, 4.6, 5.1, 5.08, 5.05mm Nobel Biocare 5.5mm	3.3mm , 3.5mm, 4.0mm, 4.1mm, 4.3mm, 4.5mm, 4.8mm, 6.0mm, 6.5mm	3.5,3.77mm, 3.75mm, 4.25mm, 4.65mm, 4.63mm, 4.6mm, 5.1mm, 5.08mm, 5.05mm	5.5mm
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.
Manufacturing Process	Machining	Machining	Machining	Machining
Abutment Sterilization	Moist Heat (Steam)	Moist Heat (Steam)	Gamma Radiation	Gamma Radiation
Abutment Angulation	30°	30°	-	-

14. **Summary of Non-Clinical Performance Testing**

Non-clinical Test data was used to support substantial equivalency. Non-Clinical testing consisted of reverse engineering of the OEM implant body, abutment and abutment screw

and tolerance analysis of platforms to ensure implant/abutment compatibility, dimensional verification and implant/abutment connection checks.
Fatigue testing was performed on worst case scenario samples in accordance with the Class II Special Controls Guidance Document and ISO 14801. Worst case scenario was defined as the smallest diameter and shortest length from each platform. Performance testing demonstrated conformance to design input and indications for use.
The evaluation was based on FDA guidance "Class II Special Controls Guidance: Root -form Endosseous Dental Implants and Endosseous Dental Implant Abutments."

Moist Heat sterilization validation testing was performed in accordance with ANSI/AAMI/ISO 17665-1: 2006 and ISO ANSI/AAMI/ISO 17665-2: 2009. Test results demonstrate a sterility assurance level of 10^{-6}.
The Argen IS Titanium Abutments have the same sterilization process and biocompatibility as previously cleared Argen and Sterngold devices.

Therefore sterility and bio-compatibility testing performed on cleared Argen devices is applicable to the proposed devices.

15. **Conclusion**

The proposed devices have similar technological characteristics, performance specifications and intended use as of its predicates.
Similar technological characteristics, performance testing data and intended use supports a determination of substantial equivalence of proposed devices to the predicate and reference devices.