September 30, 2019

DIO Corporation
% Peter Kang
Business Manager
DIO USA
3470 Wilshire Blvd, #620
Los Angeles, California 90010

Re: K190048
Trade/Device Name: UF(II) Anatomic abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 28, 2019
Received: August 30, 2019

Dear Peter Kang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K190048

Device Name
UF(II) Anatomic abutment

Indications for Use *(Describe)*
The UF(II) Anatomic abutment is intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The abutment can be used in single tooth replacements and multiple tooth restorations.

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.

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510(k) Summary

K190048

This 510(k) Summary is being submitted in accordance with requirement of 21 CFR part 807.92

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Device Information:

Trade Name: UF(II) Anatomic abutment
Common Name: Endosseous dental implant abutment
Classification Name: Abutment, Implant, Dental, Endosseous
Product Code: NHA
Panel: Dental
Regulation Number: 21 CFR 872.3630
Device Class: Class II
Date prepared: 09/26/2019

General Description

The UF(II) Anatomic abutment is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation. The anatomic abutment has scalloped margins to follow the gingival contour to provide better esthetic results with the final prosthesis. It consist of straight abutment and angled of 5º, 18º, and are made from titanium alloy conforming to ASTM F136. The anatomic abutments are pre-manufactured (stock) abutment. The abutments is provided non-sterile, this should be user steam sterilized before use.

Indication For Use

The UF(II) Anatomic abutment is intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The abutment can be used in single tooth replacements and multiple tooth restorations.

Predicate devices

The subject device is substantially equivalent to the following predicate and Reference Device:
Primary Predicate Device : P.004 RC Anatomic Abutments (K062129)
Reference Device : P.004 NC Anatomic abutment (K071357)
Neodent Implant System
CM Anatomic Abutment (K150199)
DIO UF HSA INTERNAL SUB-MERGED IMPLANT SYSTEM (K122519)

Summaries of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

	Subject Device	**Primary Predicate Device**	**Reference Device**		
Applicant	DIO Corporation	Institut Straumann AG	Straumann US (on behalf of Institut Straumann AG)	JJGC Industria E Comercio De Materiais Dentarios SA	DIO Corporation
Trade Name	UF(II) Anatomic abutment	P.004 RC Anatomic Abutments	P.004 NC Anatomic Abutment	Neodent Implant System	DIO UF HSA INTERNAL SUB-MERGED IMPLANT SYSTEM
510(K) No.	K190048	K062129	K071357	K150199	K122519
Classification Name	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)
Product Code	NHA	NHA	NHA	NHA	NHA
Class	II	II	II	II	II
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	-	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Design					
Abutment Diameters (mm)	4.21/4.49/4.84/5.11/6.14	6.5	4.0	4.7/6.0	4.5/5.5

Gingival heights	1.5/2.5/3.5/4.5/5.5	2.0/3.5	2.0/3.5	1.5/2.5/3.5	1.5/2.0/3.0/4.0/5.0
Angle	5/18	0/15	0/15	0/17	15/25
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)
Type of Retention	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained
Intended Use	The UF(II) Anatomic abutment is intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The abutment can be used in single tooth replacements and multiple tooth restorations.	The P.004 Implants are intended for immediate, delayed or conventional placement in the maxilla and/or mandibular arches to support crowns bridges or overdentures in edentulous or partially edentulous patients. They are intended for immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations.	CM Alvim Acqua Implant The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted. Facility Acqua Implant The Neodent Implant System is intended to be surgically placed in the bone of the	The DIO UF HSA Internal Sub-Merged Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit's prosthetic attachment to restore a patient's chewing function. The smaller(Ø3.8~5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The

		implants must be used. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. Meso abutments are indicated for cemented restorations particularly in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple tooth restorations.		upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. The Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures. CM Anatomic Abutment, Exact Anatomic, Lateral Anatomic, and Lateral Anatomic Abutments The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for	larger(Ø6.0~7.0) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.

				single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	
Substantial Equivalence Comparison	The UF(II) Anatomic abutment is substantially equivalent in designs, dimensions, material, indications, and technological characteristics with the identified primary predicate device. The UF(II) Anatomic abutment is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-food endosseous dental implants and endosseous dental implant abutments. The diameters and angulation of the subject device are slightly different from the predicate devices. However, the subject diameters and angulations are in the range of diameters and angulation of predicates. The Indications for Use of the subject and primary predicate device are identical other than lack of the first sentence and middle sentence for fixture. It is acceptable since the subject device is anatomic abutment only. Therefore, the indication related to fixture was excluded. Thus, the proposed indications do not increase risk nor change the intended use of the device and are found to be substantially equivalent. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.				

Non-clinical Testing

The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device. This testing included:

Sterilization Validation

Sterilization validating testing has been performed in accordance with ISO 17665-1 and ISO 17665-2 for steam sterilization. Test results have demonstrated that the SAL of 10-6 was achieved and all testing requirements were met. Sterilization validation was conducted in accordance with FDA Guidance *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*.

For the subject devices provided non-sterile status.

Fatigue Test

The fatigue test was performed on the subject device in accordance with ISO 14801:2007 Dentistry-Implants-Dynamic fatigue test for Endosseous Dental Implants. The worst case scenario was chosen based on the FDA guidance *"Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments"*.
The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Test according to ISO 14801:2007

Biocompatibility

The Biocompatibility Test are leveraged from previous submission (K122519). Biocompatibility test conducted in accordance with FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*. Abutments have the identical nature of body contact, contact duration, material formulation, manufacturing processes, and sterilization methods compared to the primary and reference devices. No new issues of biocompatibility are raised for the subject devices. FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*.
Therefore, no additional biocompatibility testing was required.

Conclusions

The UF(II) Anatomic abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, UF(II) Anatomic abutment send its predicates are substantially equivalent.