May 18, 2020

DIO Corporation
% Joyce Kwon
CEO
Provision Consulting Group Inc.
100 N. Barranca Street, Suite 700
West Covina, California 91791

Re: K193404
Trade/Device Name: UF(II) Bar holder abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 6, 2020
Received: February 18, 2020

Dear Joyce Kwon:

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.
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)*
K193404

Device Name
UF(II) Bar holder abutment

Indications for Use *(Describe)*
The UF(II) Bar holder abutment is intended to be used as a retention device in conjunction with the fixture in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.

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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K193404
510(k) Summary

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) Bar holder 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: 05/18/2020

General Description

UF(II) Bar holder abutment and set screw is used for prosthetic restoration. Bar holder abutment is intended to be used in conjunction with the fixture in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients. UF(II) Bar holder abutments are made from Ti-6Al-4V ELI (ASTM F136). The UF(II) Bar holder abutment has two type shape which are Single body type and Cap type.
The UF(II) Bar holder abutment of single body type consists of abutment, abutment screw and set screw. The UF(II) Bar holder abutment of cap type consists of abutment, abutment screw, set screw and abutment cap. Both type Bar holder abutment has Hex, Non-Hex connection. Subject abutments are only intended for multi-unit restorations. It is provided non-sterile, this should be user steam sterilized before use. It is used for overdentures with clip for bar retention. The clip is fixed to the overdenture and used to supplement the retention of the bar and denture. The bar is used to fix the abutment and overdenture. It is held in place with the set screw. The cap is used to cover the bar holder abutment Cap Type. The components--clip, bar, and cap--are included in the device system.

Indication For Use

The UF(II) Bar holder abutment is intended to be used as a retention device in conjunction with the fixture in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.

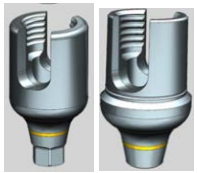
Predicate devices

The subject device is substantially equivalent to the following Predicate Device:
Primary Predicate Device: ERA® Micro 23° and 30° Female Abutment (K130408)

Reference Device: UF(II) Narrow Implant System (K161987)
DIO UF HSA INTERNAL SUB-MERGED IMPLANT SYSTEM, Ball abutment (K122519)
DIO CAD/CAM Abutment (K181037)

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	Sterngold Dental, LLC	DIO Corporation	DIO Corporation	DIO Corporation
Trade Name	Bar holder abutment	ERA® Micro 23° and 30° Female Abutment	DIO UF HSA INTERNAL SUB-MERGED IMPLANT SYSTEM, Ball abutment	UF(II) Narrow Implant System	DIO CAD/CAM Abutment
510(K) No.	Not yet assigned	K130408	K122519	K161987	K181037
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (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 CP-4 (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Surface treatment	Machined	TiN Coated	Machined	Machined	Machined
Design					N/A
Diameters (mm)	4.5	not defined	3.5	3.5	3.0/3.3/3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0
Height (mm)	6.5/7.0/8.0/9.0/	not defined	4.5/5.5/6.5/7.5/8.5/9.5	4.5/5.5/6.5/7.5/8.5/9.5/10.5	3.1~14.9

Angulation	0°	23°, 30°	0°	0°	0°~15°
Sterilization	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)
Indications For Use/ Intended Use	The UF(II) Bar holder abutment is intended to be used as a retention device in conjunction with the fixture in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.	The ERA® Micro 230 and 300 Females are intended to be used as a retention device in conjunction with the Sterngold Acid Etch Dental Implant System in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.	Ball Abutment can be used to prepare fully or partially over denture. Ball Abutment system consists of ball abutment, retainer, ball abutment cap, and ball analog.	Ball Abutment is intended for use in conjunction with the fixture in partially or fully endentulous mandibles and maxillae and used for producing denture.	DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
Substantial Equivalence Discussion	**Similarities:** UF(II) Bar holder abutment is substantially equivalent in indications for use as Primary Predicate device (K130408), while material, sterilization, angulation, packaging, manufacturing process and technological characteristics are same as its reference devices K122519, and K161987. **Differences:** The subject device and reference devices are different in shape and dimension. To support this discrepancy, we performed the fatigue test. The subject device's length is different from reference device (K161987). However, the subject device length is in the range of length of reference device (K161987). The subject device has a difference in the technological characteristic that the device is designed to maintain a denture bar for clipping a removable denture. The identified reference predicates are ball attachment types. The UF(II) Bar holder Abutment is identical in fundamental scientific technology to the predicate and reference devices 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. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate device and do not raise different questions of safety and effectiveness than the predicate.				

Non-clinical Testing

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario, (smallest diameter with maximum angulation) through fatigue 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/reference devices.

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

Sterilization Validation and Shelf Life Testing

User Sterilization Validation Report performed in K181037 was leveraged for the subject device. Sterilization validating testing in K181037 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. The subject devices are provided non-sterile status.

Biocompatibility

The Biocompatibility Test are leveraged from own reference device (K161987).

We provided the biocompatibility test report of the Ti-6Al-4V ELI (ASTM F136) in own reference device (K161987) per *the 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"*.

Ti-6Al-4V ELI (ASTM F136) used for the subject device and own reference device (K161987) is exactly same from same manufacturer. The reference device (K161987) support substantial equivalences because same manufacturing process and material are used for subject and own predicate device. No new issues of biocompatibility are raised for the subject devices. Therefore, no additional biocompatibility testing was required.

Summary of clinical testing

No clinical testing was performed for this submission.

Conclusions

The UF(II) Bar holder abutment constitutes a substantially equivalent medical device. This system has the same intended use and fundamental scientific technology as its predicate and reference devices. Therefore, UF(II) Bar holder abutment sand its predicates are substantially equivalent.