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

June 1, 2018

Re: K173975
Trade/Device Name: UF(II) Wide Fixture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 23, 2018
Received: March 5, 2018

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. 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 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,

Mary S. Runner -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

Indication for Use

510(K) Number (if known): K173975

Device Name: UF(II) Wide Fixture

Indications for Use:

The UF(II) Wide Fixture is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The larger (Ø5.9 – Ø6.9mm) 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.

Prescription Use _____X_____ AND/OR Over The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K173975

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) Wide Fixture
Classification Name: Endosseous Dental Implant
Classification: Class II
Product Code: DZE
Regulation : 21 CFR 872.3640
Date Prepared: 05/31/2018

General Description

UF(II) Wide Fixture is especially designed for use in dental implant surgery. It is intended to be surgically placed in the bone of the upper or lower jaw arches. It consists of titanium, screw-form, root-form endosseous dental implant.

Indication For Use

The UF(II) Wide Fixture is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The larger (Ø5.9 – Ø6.9mm) 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.

Predicate devices

Primary Predicate Device : DIO UF HSA Internal Sub-Merged Implant System(K122519)
Reference Device : Rescue Dental Internal Implant System (K063216)

Substantial Equivalence Comparison

The UF(II) Wide Fixture is substantially equivalent in design, function, material and indications for use to Predicate device of K122519, K063216.
The UF(II) Wide Fixture has the same material, surface treatment and similar design to the Primary Predicate device as K122519, the similar with reference devices as K063216.
The Indications for Use listed for the Subject and Primary predicate devices (K122519) do not raise new questions of substantial equivalence because smaller diameter implants are not part of this submission and all the subject devices retain the same intended use. The Indications for Use were adequately modified to reflect this difference.
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.

	Subject Device	**Primary Predicate Device**	**Reference device**
Applicant	DIO Corporation	DIO Corporation	Megagen Implant Co., Ltd.
Trade Name	UF(II) Wide Fixture	DIO UF HSA Internal Sub-Merged Implant System	RESCUE INTERNAL IMPLANT SYSTEM
Classification Name	Endosseous Dental Implant (872.3640)	Endosseous Dental Implant (872.3640)	Endosseous Dental Implant (872.3640)
510(k) No.	Not yet assigned	K122519	K063216
Product Code	DZE	DZE	DZE
Class	II	II	II
Material	Titanium Gr4	Titanium Gr4	Titanium Gr4
Surface	SLA	SLA	SLA
Width(Φ)	5.9/6.4/6.9	6.0/6.5/7.0	5.0/6.0/6.5/7.0/8.0
Length	7/8.5/10/11.5/13	7/8.5/10.5/12.5/14.5	7/8.5/10/11.5/13
Image			
Indications For Use	The UF(II) Wide Fixture is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic attachment to restore a patient's chewing function. The larger (Ø5.9 – Ø6.9mm) implants can be placed with a conventional two stage surgical process with an option for transmucosal	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 units' prosthetic attachment to restore a patient's chewing function. The smaller (Ø3.8 ~ Ø5.5) implants can be placed with a conventional two stage surgical process with an option for transmucosal	The Rescue Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially of fully edentulous individuals. These implants are intended to be used where smaller implants have failed.

	healing and are indicated for the molar region with delayed loading.	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 larger (Ø6.0 ~ Ø7.0) 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.	
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

Non-Clinical Test Data

The result of 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 and Shelf Life Testing
Sterilization validating testing has been performed in accordance with ISO 11137-1, ISO 11137-2, ISO 11137-3, ISO 11737-1, and ISO 11737-2 for gamma sterilization. Test results have demonstrated that the SAL of 10-6 was achieved and all testing requirements were met.

For the subject devices provided sterile, accelerated aging shelf life testing was conducted according to ASTM F1980 and real time testing is being conducted to support accelerated aging results.

Fatigue test
The fatigue test was performed on the subject device in accordance with ISO 14801:2016 Dentistry-Implants-Dynamic loading 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".

Biocompatibility
The Biocompatibility Test are leveraged from previous submission(K122519) such as Cytotoxicity test, Sensitization test, Irritation or Intracutaneous reactivity test, Systemic toxicity test, Sub-chronic toxicity test, Genotoxocity test and Implantation test. Also, new cytotoxicity test conducted for subject device. The subject device has the same material, surface treatment, and manufacturing process as the Primary predicate device (K122519).

Mechanical Testing

The following tests were conducted to demonstrate substantial equivalence to the predicate device:
Appearance Test confirm external appearance of subject device (smooth without crack or damage)
DimensionTest – confirm same fundamental technology through dimensional analysis
RotationalAngle Test – confirm that the subject device will not significantly rotate
Maximum Torque for dental implant screwTest – confirm equivalent rotational torque
Removal Torque for dental implant screwTest – confirm equivalent removal torque
Static Shear Strength Test accordingto ISO 14801.- confirm equivalent static shear strength
Packaging Test – confirm that the packaging is adequate and equivalent
Acid Residue Test – confirm that F-, Cl-, NO2-, NO3-, SO42-, Br- and PO43- should be less than 1ppm.
Component analysis – confirm that no foreign materials are observed on the surface.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, DIO Corporation concludes that the UF(II) Wide Fixture is substantially equivalent to predicate devices as described herein.