Dentis Co., Ltd.
% April Lee
Consultant
Withus Group Inc.
106 Superior
Irvine, California 92620

May 3, 2023

Re: K230203
Trade/Device Name: Dentis I-FIX Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 27, 2023
Received: March 27, 2023

Dear April Lee:

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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)*

K230203

Device Name
Dentis I-FIX Abutment

Indications for Use *(Describe)*
Dentis I-FIX Abutment is intended for use as an aid in prosthetic rehabilitation.

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.

510(k) Summary

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Device Information

- 510(k) number: K230203
- Trade Name: Dentis I-FIX Abutment
- Common Name: Dental Abutment System
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 05/03/2023

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K210826, Healing Abutment, Cover Screw manufactured by MegaGen Implant Co., Ltd.

Reference devices

- K083586, I-FIX SYSTEM manufactured by Dentis Co., Ltd.
- K111364, HAPTITE COATING IMPLANT SYSTEM by Dentis Co., Ltd.
- K171027, Dentis Dental Implant System manufactured by Dentis Co., Ltd.

Indication for Use:
Dentis I-FIX Abutment is intended for use as an aid in prosthetic rehabilitation.

Device Description:
Dentis I-FIX Abutment consists of I-FIX Angled Type Fixture Healing Abutment, I-FIX Angled Type Fixture Healing Abutment Screw, and I-FIX Abutment Screw.

I-FIX Angled Type Fixture Healing Abutment and I-FIX Angled Type Fixture Healing Abutment Screw are compatible with following Implant Systems:

Proprietary Name	I-FIX System (Angled Type Fixture)
Compatible Implants (K number)	K083586
Implant diameter size	Ø 2.0, 2.5, 3.0 mm
Implant length	10~16 mm

I-FIX Abutment Screw is only used with I-FIX Cemented Abutment and I-FIX Free Abutment cleared in K083586.

The dimensions of abutments are as following:

No.	Device Name	Dimension (mm)	Angulation
1	I-FIX Angled Type Fixture Healing Abutment	(D) 4.03 X (L) 3.2, 4, 5 and 7	0º
2	I-FIX Angled Type Fixture Healing Abutment Screw	(D) 2.15 X (L) 4.0, 4.8, 6.1 and 8.0	0º
3	I-FIX Abutment Screw	(D) 2.15 X (L) 4.7	0º

Tolerance of dimension for Abutments shall be within ± 1% range.

The Abutments have below featured:

Name	Uses	Surface	Materials
I-FIX Angled Type Fixture Healing Abutment	The healing Abutment is used for protecting inner hole of fixture and adjusting the appropriate height during the healing period	Non	Titanium Grade 4
I-FIX Angled Type Fixture Healing Abutment Screw			Ti-6Al-4V ELI
I-FIX Abutment Screw	I-FIX Abutment screw is used with the previously cleared devices, K083586 such as I-FIX Cemented and Free Abutment for connecting with fixture.	Non	Ti-6Al-4V ELI

I-Fix Angled Type Fixture Healing Abutment and I-FIX Angled Type Fixture Healing Abutment Screw are packaged as a set and provided sterilized. I-FIX Abutment Screw is provided non-sterilized.

Materials

- I-FIX Angled Type Fixture Healing Abutment is fabricated from pure titanium (Conforming to ASTM Standard F67)
- I-FIX Angled Type Fixture Healing Abutment Screw and I-FIX Abutment Screw are fabricated from Ti-6Al-4V ELI (Conforming to ASTM Standard F136)

Summaries of Technological Characteristics & Substantial Equivalence Discussion

I-FIX Angled Type Fixture Healing Abutment & I-FIX Angled Type Fixture Healing Abutment Screw

	Subject Device	Primary Predicate	Reference Device
K number	K230203	K210826	K171027
Manufacturer	Dentis Co., Ltd.	MegaGen Implant Co., Ltd.	Dentis Co., Ltd.
Device Name	Dentis I-FIX Abutment	Healing Abutment, Cover Screw	Dentis Dental Implant System
Model Name	I-FIX Angled Type Fixture Healing Abutment & I-FIX Angled Type Fixture Healing Abutment Screw	Healing Abutment & Scan Healing Abutment Screw	s-Clean Healing Abutment
Design			
Diameter	Ø 4.03 mm	Ø 4.0 ~ 10.0 mm	Ø 4.0, 4.5, 4.8, 5.0, 5.5, 6.0, 6.5, 7.0 and 7.5 mm
Cuff Length	0.8 mm	2.0~7.0 mm	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm
Male Screw x Pitch	M1.6 X 0.35P	M1.6 X 0.35P M1.8 X 0.35P M2.0 X 0.35P	M1.6 X 0.35P
Coating	Non	Non Screw: Anodizing	Non
Material	Body: CP Titanium Gr4 (ASTM F67) Screw: Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Titanium Gr4 (ASTM F67)
Indications for Use	Dentis I-FIX Abutment is intended for use as an aid in prosthetic rehabilitation.	MegaGen Prosthetics are intended for use as an aid in prosthetic rehabilitation.	Dentis Dental Implant System is 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 restorations. Dentis Dental Implant System serves as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implants. This is an implant abutment support prosthesis such as the artificial teeth used temporarily for the restoration of masticatory function of patients.
Sterilization	Gamma sterile	Gamma sterile	Gamma sterile
Comparison	When comparing the subject device to the primary predicate, the indication for use, use with screw, Male Screw X Pitch, function, and coating are the same. The difference between two devices are material and dimensions. To support the difference of material, K171027 was added. The dimensions of subject device are slightly smaller than the identified predicate devices; however, this difference is not an important factor to device performance. Therefore, subject device and predicate device are substantially equivalent.		

I-FIX Abutment Screw

	Subject Device	Reference Device
K number	K230203	K083586
Manufacturer	Dentis Co., Ltd.	Dentis Co., Ltd.
Model Name	I-FIX Abutment Screw	s-Clean Abutment Screw
Design		
Head Diameter	Ø 2.15 mm	Ø 2.2 mm
Length	4.7mm	4.05mm
Male Screw x Pitch	M1.6 X 0.35P	M1.6 X 0.35P
Coating	Non	Non
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	Subject Device and Reference Device have the same indications for use, function material, coating, and sterilization method. The Head diameter is different; however, this difference is not an important factor to device performance. Therefore, subject device and predicate device are substantially equivalent.	

Non-Clinical Test Data

Below tests were performed for predicate devices and leveraged for the subject device:

- Sterilization validation test on healing abutment made of Titanium Gr4 according to ISO 11137-1,2,3 referenced in K210134
- Sterilization validation test on healing abutment made of Ti-6Al-4Al ELI according to ISO 11137-1,2,3
- End User Sterilization Validation Test Report on Abutments according to ANSI/AAMI ST79, ISO 17665-1,-2, ISO 11737-1,-2, and ISO 11138-1 referenced in K111364
- Shelf Life Test on Healing Abutment according to ASTM F1980 referenced in K171027
- Biocompatibility testing according to ISO 10993-1:2009 for Pure Titanium Grade 4 or Ti-6Al-4V ELI referenced in K210134 and K16124

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

Non-clinical test data was conducted in accordance with FDA Guidance “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments”. Clinical testing was not necessary to establish substantial equivalency of the device.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic Dentis I-FIX Abutment in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. 'Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices.’ Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodied, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

Conclusion

Dentis I-FIX 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 devices. Therefore, Dentis I-FIX Abutment and its predicates are substantially equivalent.