3/23/23

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

Re: K222367
Trade/Device Name: SAVE GBR
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: February 19, 2023
Received: February 21, 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,

Sherrill Lathrop Blitzer

for Andrew 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222367

Device Name
SAVE GBR

Indications for Use *(Describe)*
The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.

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

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Device Information

- Trade Name: SAVE GBR
- Common Name: GBR System
- Classification Name: Intraosseous fixation screw or wire
- Product Code: DZL
- Panel: Dental
- Regulation Number: 872.4880
- Device Class: Class II
- Date prepared: 03/23/2023

Primary Predicate:
K170697, GBR System by Surgident

Reference Device:
K182881, Bone Screw, Bone Tack by Osstem Implant Co., Ltd.

Indications for Use:
The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.

Device Description:
SAVE GBR is manufactured by Ti-6Al-4V ELI. The SAVE GBR is composed of GBR Screw and Bone Tack and these screws and tacks are used to fix barrier membranes in bone regeneration procedures.

The diameter of the GBR screw is ø1.4 and length is 3.9, 4.38, 5.9, 6.38, 7.9 and 8.38mm.
The diameter of the Bone Tack is 2.5 and length is 2.6 and 4.1mm.

These screws and tacks are implanted for a maximum duration of 6 months. The SAVE GBR is provided sterile.

The subject device is compatible with the OssBuilder membrane cleared in K172354.

Materials:

- GBR Screw and Bone Tack are manufactured by Ti-6Al-4V ELI according to ASTM F136

Summaries of Technology Characteristics

The subject device is substantially equivalent to the current cleared devices. They are substantially equivalent in intended use, material and product spec as diameter and length. Comparison demonstrating Substantial Equivalence follows:

1. GBR Screw

	Subject Device	**Primary Predicate**	**Reference Device**
Applicant	Dentis Co., Ltd.	Surgident	Osstem Implant Co., Ltd
Trade Name	SAVE GBR	GBR System	Bone Screw, Bone Tack
510(k) No.	K222367	K170697	K182881
Classification Name	Intraosseous Fixation screw or wire	Intraosseous Fixation screw or wire	Intraosseous Fixation screw or wire
Product Code	DZL	JEY, DZL	DZL
Class	Class II	Class II	Class II
Description			
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Screw Diameter (mm)	Ø1.4	Ø0.85, Ø1.4, Ø1.6 and Ø2.0	Ø1.4 and Ø1.95
Screw Length (mm)	3.9, 5.9 and 7.9	3.0, 4.0, 5.0, 6.0, 8.0, 10.0 and 12.0	4.0, 6.0, 8.0, 10.0, 12.0, 14.0 and 16.0
Single Use	Yes	Yes	Yes
Sterile	Gamma Sterilization	End User Sterilization	Gamma Sterilization
Shelf Life	8yeasrs	N/A	8years
Surface Treatment	N/A	Anodizing	N/A
Indications For Use	The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.	The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.	Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. Bone Tack is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.
Substantial Equivalence Comparison	The subject GBR screw is substantially equivalent in dimensions, material, indications, and technological characteristics with the identified primary predicate device(K170697). The difference between the subject and primary predicate is the screw design, anodizing and sterilization. However, the general shapes of both devices are very similar and anodizing does not affect product's fundamental technologies or indications. To support the difference of sterilization, K182881 was added. Therefore, the subject device is substantial equivalent.		

2. Bone Tack

	Subject Device	**Primary Predicate**	**Reference Device**
Applicant	Dentis Co., Ltd.	Surgident	Osstem Implant Co., Ltd
Trade Name	SAVE GBR	GBR System	Bone Screw, Bone Tack
510(k) No.	K222367	K170697	K182881
Classification Name	Intraosseous Fixation screw or wire	Intraosseous Fixation screw or wire	Intraosseous Fixation screw or wire
Product Code	DZL	JEY, DZL	DZL
Class	Class II	Class II	Class II
Description			
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Head Diameter	Ø2.5	Ø2.5	Ø2.5
Screw Diameter (mm)	Ø0.85	Ø0.85	Ø0.7
Length (mm)	3.5 and 5.0	3.5 and 5.0	3.0
Surface Treatment	Anodizing (Purple, Blue)	Anodizing (Purple, Blue)	Anodizing (Purple, Blue)
Sterile	Gamma Sterilization	End User Sterilization	Gamma Sterilization
Indications For Use/ Intended Use	The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.	The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.	Bone Screw is used to stabilize and fixate bone grafts, bone filling material, and/or barrier membranes used for regeneration of bone in the oral cavity. Bone Tack is indicated for use to stabilize and support bone graft and/or fractured bone segments with or without bone plates or titanium mesh in oral and maxillofacial site defects.
Substantial Equivalence Comparison	The subject bone Tack is substantially equivalent in designs, material, indications and technological characteristics with the identified primary predicate device(K170697). The difference between two products is sterilization. To support this discrepancy, K182881 was added. Therefore, the subject device is substantial equivalent.		

Non-Clinical Testing

Non-clinical testing data are submitted, referenced, or relied upon to demonstrate substantial equivalence.

Sterilization and Shelf Life:
The sterilization, shelf-life, and packaging testing was conducted on a worst-case test article representative of the final, finished subject device according to ISO 11137-1, ISO 11137-2 and ASTM F1980-07.

Bacterial Endotoxin Test according to ANSI/AAMI ST72:2011, USP <161>, and USP <85> for subject device was referenced in K192688.
Since endotoxin testing cannot be conducted on every batch in our company, alternative to batch testing was chosen with the sampling plan used for the in-process testing and/or finished product release, as recommended in the FDA guidance, Pyrogen and Endotoxins Testing: Questions and Answers". According to this guidance, we determined that begin with maximum coverage and adjust our sampling plans as they gain confidence in the prevention of endotoxins in their manufacturing processes.

Biocompatibility Evaluation:
Biocompatibility tests such as cytotoxicity, sensitization and irritation testing according to ISO 10993-1 performed on the abutments of K210080 can be leveraged for the subject device because both devices have the same material and manufacturing process. The results of the testing demonstrated the subject device is biocompatible.

Mechanical Properties:
Mechanical tests such as torsion, driving torque and axial pullout strength for subject device SAVE GBR and predicate device are conducted under the worst-case scenario in accordance with ISO 19023 and ASTM F543-17 Standard Specification that test method for metallic medical bone screw to support the requirement of subject device.
For GBR screw, 3 tests as torque, torsion and pull-out were conducted.
For Bone Tack, 2 tests as torsion and pull-out were conducted. Toque test is not conducted for Bone Tack since the bone tack is inserted by hitting with mallet. Torque test require for only implantation medical device that is implanted by turning, which is not subject to the subject Bone Tack.

MR Environment Condition:
Non-clinical worst-case MRI review was performed to evaluate the SAVE GBR 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 bodies, 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

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Dentis Co., Ltd. concludes that the SAVE GBR is substantially equivalent to the predicate devices as herein.