February 7, 2023

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

Re: K222451
Trade/Device Name: SAVE GBR
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 5, 2023
Received: January 6, 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
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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)*

Device Name
SAVE GBR

Indications for Use *(Describe)*
SAVE GBR is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

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

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Device Information

- Trade Name: SAVE GBR
- Common Name: GBR System
- Classification Name: Endosseous Dental Abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 02/07/2023

Predicate Devices:
Primary Predicate
K172354, Ossbuilder System by Osstem Implant Co., Ltd

Reference Device
K171027, Dentis Dental Implant System by Dentis Co., Ltd.
K181854, Ossbuilder System by Osstem Implant Co., Ltd
K140600, SMARTbuilder by Osstem Implant Co., Ltd.
K210080, Dentis s-Clean s-Line Mini by Dentis Co., Ltd.

Indication for Use:
SAVE GBR is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

Device Description:
The SAVE GBR consists of Healing Cap, Cover Cap and Spacer. The SAVE GBR are manufactured by Ti-6Al-4V ELI and used with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.

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

The dimension of the device is as below:

No.	Product	Diameter	Length
1	Healing Cap	Ø4.5 and 5.5	6.0 and 7.0mm
2	Cover Cap	Ø4.5	4.0mm
3	Spacer	Ø4.5	7.2 and 8.2mm

The healing cap and cover cap have same functions and uses but have different design and name.
The SAVE GBR are removed from the patient after such time when sufficient bone regeneration is done.
The compatible fixture with the subject device is as below.

No.	Trade Name	Product Name	Fixture Size	K number
1	s-Clean SQ-SL Implant System Regular	s-Clean SQ-SL Fixture	Ø5.2 x 7.0, 7.5, 9.5, 11.5 and 13.5	K210132

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. Healing Cap

	Subject Device	Primary Predicate	**Reference Device**
Applicant	Dentis Co., Ltd.	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
Trade Name	SAVE GBR	Ossbuilder System	Ossbuilder System
510(k) No.	K222451	K172354	K181854
Classification Name	Endosseous Dental Abutment	Endosseous Dental Abutment	Endosseous Dental Abutment
Product Code	NHA	JEY, NHA	DZL, NHA
Class	Class II	Class II	Class II
Description			
Material	Ti-6Al-4V ELI (ASTM F136)	Pure Titanium (ASTM F67)	Ti-6Al-4V ELI (ASTM F136)
Diameter	Ø4.5 and Ø5.5	Ø4.0 and Ø5.0	Ø4.0 and Ø5.0
Length (mm)	6.0 and 7.0mm	7.0 and 8.0mm	7.0 and 8.0mm
Sterile	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	8 years	8 years	8 years
Indications For Use/ Intended Use	SAVE GBR is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.
Features	Healing Cap is used with internal type of anchor.	Healing Cap is used with internal type of anchor.	Healing Cap is used with internal type of anchor.
Principles of operation	Used with non-resorbable membrane for bone regeneration	Used with non-resorbable membrane for bone regeneration	Used with non-resorbable membrane for bone regeneration
Substantial Equivalence Comparison	The subject healing cap is substantially equivalent in designs, material, indications, sterilization, shelf life, compatible membrane, and technological characteristics with the primary device (K172354). The difference between the subject and primary predicate is material. To support the different material, K181854 was added which is Ti-6Al-4V ELI (ASTM F136). Therefore, the subject device is substantial equivalent.		

2. Cover Cap

	Subject Device	**Primary Device**
Applicant	Dentis Co., Ltd.	Osstem Implant Co., Ltd
Trade Name	SAVE GBR	Ossbuilder System
510(k) No.	K222451	K172354
Classification Name	Endosseous Dental Abutment	Endosseous Dental Abutment
Product Code	NHA	JEY, NHA
Class	Class II	Class II
Description		
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Diameter	Ø4.5	Ø4.0
Length (mm)	4.0mm	4.3mm
Sterile	Gamma Sterilization	Gamma Sterilization
Shelf Life	8 years	8 years
Indications For Use/ Intended Use	SAVE GBR is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.
Feature	The Cover Cap is used with internal type of Anchor.	The Cover Cap is used with internal type of anchor
Principles of operation	Used with non-resorbable membrane for bone regeneration	Used with non-resorbable membrane for bone regeneration
Substantial Equivalence Comparison	The subject cover cap is substantially equivalent in designs, material, indications, sterilization, shelf life, compatible membrane, and technological characteristics with the primary predicate (K172354). The difference between the subject and primary predicate is dimension. The difference of diameter and length is not important to affect the function of safety. Therefore, the subject device is substantial equivalent.	

3. Spacer

	Subject Device	**Primary Device**	**Reference Device**
Applicant	Dentis Co., Ltd.	Osstem Implant Co., Ltd	Osstem Implant Co., Ltd
Trade Name	SAVE GBR	Ossbuilder System	Ossbuilder System
510(k) No.	K222451	K172354	K140600
Classification Name	Endosseous Dental Abutment	Endosseous Dental Abutment	Endosseous Dental Abutment
Product Code	NHA	JEY, NHA	NHA
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)
Diameter	Ø4.5	Ø3.1~5.0	Ø3.2~5.1

Length (mm)	7.2 and 8.2mm	4.45~9.5	7.0~15
Sterile	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Shelf Life	8 years	8 years	8 years
Indications For Use/ Intended Use	SAVE GBR is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	OssBuilder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	SMART Builder System is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.
Feature	The Spacer is external type of anchor	The OB Anchor is internal type of anchor	The SB Anchor is external type of anchor
Principles of operation	Used with non-resorbable membrane for bone regeneration	Used with non-resorbable membrane for bone regeneration	Used with non-resorbable membrane (K120951) for bone regeneration
Substantial Equivalence Comparison	The subject spacer is substantially equivalent in general design, dimensions, material, indications, sterilization, shelf life, compatible membrane, and technological characteristics with the primary predicate (K172354). The difference between the subject and primary predicate is design, especially head screw shape. To support this discrepancy, K140600 was added, which has the similar shape of the device. 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 and shelf life test were performed on predicate healing abutment, K171027 and can be leveraged for subject device since both devices have the same material, sterilization method, packaging method, and manufacturing process as the subject device according to ISO11137-1, ISO11137-2 and ISO11737-3.

Bacterial Endotoxin Test according to ANSI/AAMI ST72:2011, USP <161>, and USP <85> for subject device was referenced in K210080.
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".

Reverse Engineering
The pores of the Osstem non-resorbable membranes (K172354) which attach to the abutment were measured and compared to the diameters of the subject device in order to demonstrate compatibility.

Biocompatibility Evaluation:
Biocompatibility tests according to ISO 10993-1 performed on the abutments of K210080 can be leveraged for the subject device because both devices have same material and manufacturing process.

MR Environment Condition:

Non-clinical worst-case MRI review was performed to evaluate the GBR System 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.