Warantec Co., Ltd,
Younggwang Choi
RA Team Manager
411~412, 474, Dunchon-dearo, Jungwon-gu
Seongnam-si, Gyeonggi-do 13229
REPUBLIC OF KOREA

May 12, 2023

Re: K221969
Trade/Device Name: IU Implant System Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 14, 2023
Received: April 14, 2023

Dear Younggwang Choi:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221969

Device Name
IU Implant System Abutment

Indications for Use *(Describe)*
The Warantec dental abutment is intended to be used with the root-form endosseous dental implant to 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.

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WARANTEC

510(k) Summary – K221969

May 10, 2023

1. Submitter

	Submitter
Name	WARANTEC Co., Ltd.
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Phone/Fax	+82-2-3675-5851/ +82-2-3675-5853
Contact person	Younggwang Choi / RA ygchoi@oneplant.co.kr
Summary Date	May 10, 2023

2. Device information

a) Trade Name : IU Implant System Abutment

b) Common Name : Endosseous Dental Implant Abutment

c) Classification Name : Endosseous Dental Implant Abutment

d) Product Code : NHA

e) Regulation Number : 872.3630

f) Class of device : Class II

g) Panel : Dental

3. Predicate devices

a) Primary Predicate Device:

IU Implant System / Warantec Co., Ltd. / K172345

b) Reference Device:

ONEPLANT Dental Implant System / Warantec Co., Ltd. / K081748

Implantium® / SuperLine® Prosthetics / Dentium Co., Ltd. / K160828

4. Device description

The IU Implant System Abutment is a dental implant superstructure made of titanium alloy. It is an abutment used to support or maintain the restoration after the implantation of the fixture in the oral cavity.

The abutments are provided non-sterile and should be sterilized before use.

5. Indication for use

The Warantec dental abutment is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation.

6. Substantial equivalence comparison

The IU Implant System is similar designs and dimensions, and has the same material, intended use, surface treatment and technological characteristics as the identified primary predicate device (K172345) and reference devices (K081748 / K160828). When compared with predicate device, no new questions of substantial equivalence have been raised for the IU Implant System Abutment.

Device Name	Indication for use
IU Implant System Abutment (Subject device)	The Warantec dental abutment is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation.
IU Implant System (Primary Predicate Device: K172345)	The IU Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.
ONEPLANT Dental Implant System (References Predicate Device: K081748)	ONEPLANT is designed for use in dental implant Surgery. These are intenided for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, screw retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.
Implantium® / SuperLine® Prosthetics (References Predicate Device: K160828)	Implantium® SuperLine® Prosthetics is intended for use as an aid in prosthetic rehabilitation

The subject device (IU system abutment) has substantially the equivalent in indications and design principles as the predicate and reference devices listed above.

All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and prosthetic rehabilitation of the edentulous maxilla and mandible.

The differences between the target device IFUS(Indications for Use Statements) and the predicate and reference device are related to the specific device names, design feature, compatible implant lines.

None of these differences impact substantial equivalence. because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Device comparison

- Angled Abutment

	IU Implant System Abutment (Subject Device)		ONEPLANT Dental Implant System (References Predicate)	Dentium Implantium® & SuperLine® Prosthetics (References Predicate)
Company Name	Warantec Co., Ltd.		Warantec Co., Ltd.	DENTIUM Co., Ltd.
510(k) Number	New Device		K081748	K160828
Classification and Product Code	Class II; 872.3630; NHA			
Design				
Material	Ti 6Al 4V ELI (ASTM F136)		Ti 6Al 4V ELI (ASTM F136)	Pure Titanium Grade4 (ASTM F67)
Surface Treatment	None		None	None
Connection	Internal Hex Connection		Internal Hex Connection	Internal Hex Connection
Angulation	15°	17°	20°	15°, 25°
Diameter	4.0~5.0mm		5.0mm	4.5~5.5mm
Post height	6, 8mm	8mm	6, 8mm	7mm
Gingival Height	2~6mm	2~4mm	2~5mm	1.5mm, 2.5mm, 3.5mm
Restoration type	Single & Multi	Single & Multi	Single & Multi	Single & Multi
Similarities	The subject and reference devices have same intended use, functions, materials and general shape (design).			
Differences	The differences between the subject device and the reference predicate device are the surface treatment, angulation, and dimensional range. These minor differences don't affect product's fundamental function. K160828 was selected as the reference device to support the difference in dimensions such as diameter and length and the angle difference of the abutment, including the dimensions and angle range of the subject device. Therefore, the subject device and the reference devices are substantially equivalent.			

7. Non-clinical testing data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

• Steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10-6.

• Biocompatibility of Ti-6Al-4V ELI (ASTM F136) demonstrated by the referenced Warantec submission, K172345, using the same materials and manufacturing processes as the subject device.

• Fatigue testing was conducted on the worst case according to ISO 14801:2016 and the FDA Special Controls Guidance Document for Root-form Endosseous Dental Implants and Endosseous Dental Abutment.

• Non-clinical worst-case MRI review was performed to evaluate the metallic IU System Abutment devices 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 compositions. The 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.

No clinical data were included in this submission.

8. Conclusion

The subject device has the similar technological characteristics to the predicate device, main material, indication for use and design.

Based on the information provided for this premarket notification of Warantec Co., Ltd. conclude that IU System Abutment are substantially equivalent to predicate devices.