October 2, 2023

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

Re: K221972
Trade/Device Name: Warantec Custom Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 6, 2023
Received: September 6, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K221972

Device Name
Warantec Custom 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.

All digitally designed abutments for use with Warantec Custom Abutments are intended to be sent to a Warantec-validated milling center for manufacture.

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 – K221972

September 28, 2023

1. Submitter

	Submitter
Name	WARANTEC Co., Ltd.
Address	411-412, 474, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13229, Rep. of Korea
Phone/Fax	+82-2-3675-5851/ +82-2-3675-5853
Contact person	Younggwang Choi / RA ygchoi@oneplant.co.kr
Summary Date	September 28, 2023

2. Device information

a) Trade Name : Warantec Custom 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 deivces”

a) Primary Predicate Device:

Prosthetic System / OSSTEM Implant Co., Ltd. / K110308

b) Reference Device:

Ti-Blank / Dentium Co., Ltd. / K161713

Elos Accurate® Customized Abutment / Elos Medtech Pinol A/S / K192457

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

4. Device description

Warantec Custom Abutments are used for cement-retained crowns and bridges using customized abutment considering based on the patient's mouth using CAD/CAM system. That is customized abutment considering shape of the final prosthesis based on the patient's mouth model using CAD/CAM system during the manufacturing. The Warantec Custom Abutment are made of Ti-6Al-4V ELI (ASTM F136). These devices are supplied non-sterile and autoclaved by the end user and intended for single use only. Warantec Custom Abutments are compatible with IU Implant System.

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.

All digitally designed abutments for use with Warantec Custom Abutments are intended to be sent to a Warantec-validated milling center for manufacture.

6. Substantial equivalence comparison

The Waratnec Custom Abutment is similar designs and dimensions, and has the same material, intended use, surface treatment and technological characteristics as the identified primary predicate device (K110308) and reference devices (K161713/K192457/K172345). When compared with predicate device, no new questions of substantial equivalence have been raised for the Warantec Custom Abutment.

<table>
<tr><th>Device Name</th><th>Indication for use</th></tr>
<tr><td>Warantec Custom Abutment
(Subject device)</td><td>The Warantec dental abutment is intended to be used with the root-form endosseous dental implant to aid in prosthetic rehabilitation.

All digitally designed abutments for use with Warantec Custom Abutments are intended to be sent to a Warantec-validated milling center for manufacture.</td></tr>
<tr><td>Prosthetic System
(Primary Predicate Device: K110308)</td><td>Prosthetic System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.</td></tr>
<tr><td>Dentium CAD/CAM Abutments
(References Predicate Device: K161713)</td><td>Dentium abutments are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. All digitally designed abutments for use with Dentium CAD/CAM Abutments are intended to be sent to a Dentium-validated milling center for manufacture.</td></tr>
<tr><td>Elos Accurate® Customized Abutment
(References Predicate Device: K192457)</td><td>The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.
The Elos Accurate® Customized Abutments are compatible with the implant systems listed in table 1:
Table 1.
<table>
<tr><th>Elos Accurate Customized Abutment – Model Type</th><th>Platform compatibility</th><th>Platform diameter [mm]</th><th>Implant Body diameter [mm]</th></tr>
<tr><td>AB-NBR43</td><td>Nobel Replace RP</td><td>4.3</td><td>4.3</td></tr>
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<tr><td></td><td>
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<tr><td>AB-NBR50</td><td>Nobel Replace WP</td><td>5</td><td>5</td></tr>
<tr><td>AB-NBR60</td><td>Nobel Replace 6.0</td><td>6</td><td>6</td></tr>
<tr><td>AB-NBA35</td><td>Nobel CC NP</td><td>3.5</td><td>3.5 &3.75</td></tr>
</table>
All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are only
intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility.
</td></tr>
<tr><td>IU Implant System (References Predicate Device: K172345)</td><td>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.</td></tr>
</table>

The subject device (Warantec Custom 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 rehabilitation of the edentulous maxilla and mandible.

The only differences between the target device IFUS(Indications for Use Statements) and the reference device are specific device names, compatible implant lines and CAD/CAM manufacturing/milling descriptions and requirement for the use of validated milling centers.

None of these minor 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

Device Name	Subject Device	Primary Predicate	Referenced Predicate	Referenced Predicate
	Warantec Custom Abutment	Prosthetic System	Ti-Blank	Elos Accurate® Customized Abutment
Company	Warantec Co., Ltd.	OSSTEM Implant Co., Ltd.	Dentium Co., Ltd.	Elos Medtech Pinol A/S
Predicate 510k	New Device	K110308	K161713	K192457
Classification and Product Code	Class II; 872.3630; NHA	Class II; 872.3630; NHA	Class II; 872.3630; NHA	Class II; 872.3630; NHA
Type of abutment	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge	Abutments for single tooth or cemented bridge
Characteristics	Customizable to desired shape	Customizable to desired shape	Customizable to desired shape	Customizable to desired shape
Predicate Material	Titanium Alloy 6Al-4V (ASTM F136)	Titanium alloy (ASTM F136)	Pure Ti Grade 4 (ASTM F67)	Titanium Alloy 6Al-4V ELI, medical grade 5
Surface Treatment	None	None	None	None
Angulation (°)	0 to 30°	0 to 30°	0 to 30°	0 to 30°
Total Length	14.4mm	Not defined	Not defined	Not defined
Post Height(mm)	4.0~8mm	Not defined	Not defined	4.0~13mm
Diameter(mm)	3.6~6.0mm	3.6-5.0mm	3.6-5.0mm	3.5~6.0mm
Gingival Height	0.5~4.0mm	Not publicly available	Not publicly available	0.5mm ~ 5.0mm
Minimum Thickness	0.4 mm	Not defined	Not defined	0.4 mm
Use	Prescription	Prescription	Prescription	Prescription
Production	Turned and Milled	Turned and Milled	Turned and Milled	Turned and Milled

The subject device is substantially equivalent to the predicate device in design, function, manufacture and intended use.

All devices are cylindrical titanium abutments with a precision implant/abutment interface for use in fabricating a patient-specific abutment.

The subject device is different from the predicate device in implant/abutment interface, specific cylinder size, and specific abutment diameters. However, the subject device sizes are within the size range of the primary predicate.

Additionally, the Indications for Use of the subject and primary predicate device are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing, and identification of reference device for compatible implant bodies. Both the predicate and subject devices are intended to be milled into patient specific abutments using CAD/CAM technology under the manufacturing control of the sponsor.

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.

Therefore, these minor differences do not affect the determination of substantial equivalence.

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 Warantec Custom Abutment are substantially equivalent to predicate devices.