December 20, 2023

Cowellmedi Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave, STE 160
Irvine, California 92612

Re: K231411
Trade/Device Name: INNO SLA Submerged Hybrid Ti-Base System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 20, 2023
Received: November 21, 2023

Dear Priscilla Chung:

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)*
K231411

Device Name
INNO SLA Submerged Hybrid Ti-Base System

Indications for Use *(Describe)*

INNO SLA Submerged Hybrid Ti-Base System is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations. All digitally designed zirconia superstructures for use with the INNO SLA Submerged Hybrid Ti-Base System are intended to be sent to a Cowellmedi 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(K231411)

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: __ Dec 19, 2023___

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	INNO SLA Submerged Hybrid Ti-Base System
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Classification:	Class II, 21 CFR 872.3630
Classification Product Code:	NHA

4. Predicate Device:

- Primary Predicate Device: URIS Base (K200817) by TruAbutment Korea Co., Ltd.
- Reference Device: Preat Abutment (K183518) by Preat Corporation
- Reference Device: BioHorizons CAD/CAM Abutments (K151621) by BioHorizons Implant Systems, Inc.

5. Device Description:

INNO SLA Submerged Hybrid Ti-Base System consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment). These two pieces together form the final abutment. Ti-base Abutment System is made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. The zirconia material is InCoris Zi, cleared under K123664, and the cement is RelyX Unicem 2Automiz, cleared under K100756. Zirconia CAD/CAM abutment or superstructure that composes the final prosthetics is intended to be designed and milled, according to the prosthetic planning and patient clinical situation. It is compatible with the following systems:

- INNO SLA Submerged Implant System(k132242) by Cowellmedi Co., Ltd.

The system offers the following three types of Ti-Base with a screw that fix the abutment into the fixture.

- Hybrid S Ti-Base
- Hybrid L Ti-Base
- Hybrid A Ti-Base

6. Indications for Use:

INNO SLA Submerged Hybrid Ti-Base System is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations. All digitally designed zirconia superstructures for use with the INNO SLA Submerged Hybrid Ti-Base System are intended to be sent to a Cowellmedi validated milling center for manufacture.

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Sterilization validating testing has been performed in accordance with ISO 17665-1 and ISO 17665-2 for steam sterilization.
- Biocompatibility testing has been performed in accordance with ISO 10993-3, 5, 6, 10, 11, and 23.
- Fatigue test in accordance with ISO 14801
- MR Environment Condition
  Non-clinical worst-case MRI review was performed to evaluate the INNO SLA Submerged Hybrid Ti-Base System in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry 0., 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.

8. Substantial Equivalence

Comparison Chart

	Subject Device	Primary Predicate Device	Reference Device	
510(K) No.	K231411	K200817	K183518	K151621
Applicant	Cowellmedi Co., Ltd.	TruAbutment Korea Co., Ltd.	Preat Corporation	BioHorizons Implant Systems, Inc.
Trade Name	INNO SLA Submerged Hybrid Ti-Base System	URIS Base	Preat Abutment	BioHorizons CAD/CAM Abutments
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)
Product Code	NHA	NHA	NHA	NHA
Material	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Ti-6Al-4V (ASTM F136); additionally, Y-TZP Ceramic for Titanium Base Abutment
Indications For Use/ Intended Use	INNO SLA Submerged Hybrid Ti-Base System is intended for use in conjunction with the fixture in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit cement retained restorations. All digitally designed zirconia superstructures for use with the INNO SLA Submerged Hybrid Ti-Base System are intended to be sent to a Cowellmedi validated milling center for manufacture.	URIS OMNI Narrow System is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors, in support of single or multiple-unit restorations including: cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The URIS OMNI Prosthetic abutments are intended for use with URIS OMNI dental implants to provide support for prosthetic restorations such as crowns, bridges, or over-dentures. All digitally designed abutments and/or coping for use with URIS OMNI Prosthetic abutments are	Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. All digitally designed custom abutments for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture. Compatible Implant Systems Compatible Implant System / Implant Body Diameter (mm) / Implant Platform Diameter (mm) 3i OSSEOTITE® Certain® / 3.25 / 3.4 4.0 / 4.1 5.0 / 5.0 6.0 / 6.0 Astra Tech OsseoSpeed™ / 3.0 / 3.0 3.5, 4.0 / 3.5/4.0 4.5, 5.0 / 4.5/5.0 BioHorizons Tapered Internal / 3.0 / 3.0 3.5 / 3.5 4.0 / 4.5 HIOSSEN ET III / 3.5 / Mini 4.0, 4.5, 5.0, 6.0, 7.0 / Regular Implant Direct Legacy / 3.2 / 3.0 3.7, 4.2 / 3.5 4.7, 5.2 / 4.5 5.7, 7.0 / 5.7 MegaGen AnyRidge / 3.5, 4.0, 4.5, 5.0, 5.5 / 4.5 Neoss / 3.5, 4.0, 4.5, 5.0, 5.5 / 4.5 NobelActive® / 3.5 / NP 4.3, 5.0 / RP Nobel Replace™ / 3.5 / NP 4.0, 4.3, 5.0 / RP 5.0 / WP 6.0 / 6.0 Straumann® Bone Level / 3.3 / NC 4.1, 4.8 / RC Straumann® Tissue Level / 3.3, 4.1, 4.8 / RN 4.8, 6.5 / WN Zimmer Screw-Vent®/Tapered Screw-Vent® / 3.3, 3.7, 4.1 / 3.5 4.7 / 4.5 6.0 / 5.7	All digitally designed abutments and/or copings for use with BioHorizons CAD/CAM Abutments are intended to be sent to a BioHorizons-validated milling center for manufacture. BioHorizons abutments designed using CAD/CAM techniques must fulfill the BioHorizons allowable range of design parameters.

	Subject Device	Primary Predicate Device	Reference Device	
		intended to be sent to a TruAbutment-validated milling center for manufacture.		
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Cement-retained, Screw-retained
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/Implant Platform Diameter (mm)	3.5~6 mm	Narrow 2.6 Regular 3.3	3.0~6.5mm	3.0mm, 3.5mm, 4.5mm, 5.7mm
Design Limits (Min.~Max.)	Maximum Angulation 20° Maximum Cuff Height 5.0mm Minimum Gingival Height, 0.5mm Minimum Diameter Ø 5.0mm Minimum Thickness 0.4mm Minimum Post Height 4.0mm	Maximum Angulation 15° Maximum Cuff Height 5mm Minimum Diameter Ø 5.0mm Minimum Thickness 0.4mm Minimum Post Height 4~6mm	Maximum Angle 30° Minimum Thickness 0.5 mm Minimum Post Height for single-unit restoration 4.0 mm Maximum Gingival Height 1.5 mm to 2.65 mm (varies by implant line).	Custom Ti (blanks): 0°-30° Ti Base (ceramic): 0°-20°
Abutment/ Implant Interface	Internal Connection	Internal Connection	Internal Connection	Internal Connection
Sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

Substantial Equivalence Discussion

The subject device (INNO SLA Submerged Hybrid Ti-Base System) is substantially equivalent to the primary predicate device (URIS Base, K200817). The subject device and the predicate device have identical intended uses and similar technological characteristics. The wording of the indications for use statement between the subject and the predicate devices is slightly different, however, the fundamental intended use is the same and has no difference.
They are made of Ti-6Al-4V ELI, and have similar internal implant interface connections, and use similar material for restoration. Both devices have identical design parameters except for angle. We identified reference devices which cover the size of the platform diameter and the angle range of the subject device.
We also perform fatigue testing, and the result supports that the subject device is substantially equivalent to the predicate device in the market.

9. Conclusion:

Based on the testing results, Cowellmedi Co., Ltd. concludes that the INNO SLA Submerged Hybrid Ti-Base System is substantially equivalent to the predicate devices.