January 25, 2022

Cowellmedi Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K201323
Trade/Device Name: INNO SLA Submerged Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 21, 2021
Received: December 23, 2021

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 (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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201323

Device Name
INNO SLA Submerged Implant System

Indications for Use *(Describe)*
The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

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

(K201323)

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

Date: 1/24/2022

1. Submitter

Cowellmedi Co., Ltd.
48, Hakgam-daero 221beon-gil,
Sasang-gu, Busan,
46986, Republic of Korea

2. U.S Agent/Contact Person

Priscilla Chung
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3. Device

- Trade Name: INNO SLA Submerged Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: NHA
- Classification regulation: 21CFR872.3630

4. Predicate Device:

- **Primary Predicate Device:**
  INNO SLA Submerged Implant System by Cowellmedi Co., Ltd. (K132242)

- **Reference Predicate Device:**
  Locator Implant Anchor Abutment for Endosseous Dental Implant by Zest Anchors, Inc. (K072878)

5. Description:

The INNO SLA Submerged Implant System offers the following components.
The components below are used with the fixtures and the cover screws that were cleared under K132242.

No	Component
1	Healing Abutment Type A Ø7.5 x 10.7mm Ø 8.5 x 10.7 mm Ø 9.5 x 10.7mm
2	Type B Ø 6.5 x 5.9, 6.9, 7.9, 8.9, 9.9, 11.9 mm Ø 7.5 x 5.9, 6.9, 7.9, 8.9, 9.9, 11.9 mm Ø 8.0 x 5.9, 6.9, 7.9, 8.9, 9.9, 11.9 mm Ø 8.5 x 5.9, 6.9, 7.9, 8.9, 9.9, 11.9 mm Ø 9.5 x 5.9, 6.9, 7.9, 8.9, 9.9, 11.9 mm
3	Angulated Abutment Ø 4.5 x 11.9, 12.9, 13.9, 14.9mm Ø 4.8 x 9.4, 10.4, 11.4mm Ø 5.5 x 11.9, 12.9, 13.9, 14.9mm
5	Temporary Abutment Ø 4.5 x 13.65,13.9mm
6	Sonator S Abutment Ø 3.87 x 8.3, 9.3, 10.3, 11.3, 12.3, 13.3mm
7	Sonator A Abutment Ø 3.87 x 7.15, 8.7mm
8	Screw Ø 2.15 x 6.5, 7.5, 8.5mm Ø 2.2 x 7.8, 8.8, 9.8mm Ø 2.28 x 5mm Ø 2.45 x 8.5mm

6. Indication for use:

The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

7. Basis for Substantial Equivalence

Substantial Equivalence Discussion

The INNO SLA Submerged Implant System is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design. There are slight differences mostly in abutment size options, however, it is very minor not affecting substantial equivalence.
We have performed the fatigue test to make sure the differences do not raise an issue in safety and effectiveness and the test result of the test supported substantial equivalence.
Based on the information and test results provided in submission, we conclude that the subject device is substantially equivalent to the predicate devices.

Comparison Chart

- **Healing Abutment**

	Subject Device	Predicate Device	Remark
510(k) Number	K201323	K132242	
Device Name	Healing Abutment for INNO SLA Submerged Implant System	Healing Abutment for INNO SLA Submerged Implant System	
Manufacturer	Cowellmedi Co., Ltd.	Cowellmedi Co., Ltd.	
Indications for Use	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	same
Appearance			same and similar
Diameter	6.5, 7.5, 8.0, 8.5, 9.5mm	4.1, 4.5, 4.9, 5.5, 5.95, 6.5mm	large diameter
Post Height	2, 5mm	2, 3, 4, 5, 6, 7, 9mm	same
Gingival Height	1, 2, 3, 4, 5, 7mm	1, 2, 3, 4, 5, 7mm	same
Connection Interface	Hex, Non-hex	Hex, Non-hex	same
Surface treatment	N/A	N/A	same
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	same
Angulation	0°	0°	same
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	same
Principle of operation	This component is intended to protect the inner configuration of the implant during the healing process and maintain, stabilize and form the soft tissue during this phase.	This component is intended to protect the inner configuration of the implant during the healing process and maintain, stabilize and form the soft tissue during this phase.	same
Substantial Equivalence Discussion			

The subject device has the same intended use, material, surface treatment, and design as the predicate device. This 510k is to add some more size options for diameter. The wider range is to meet each patient needs and larger diameter does not a concern in performance or safety.

- **Angulated Abutment**

	Subject Device	Predicate Device	Remark
510(k) Number	K201323	K132242	
Device Name	Angulated Abutment for INNO SLA Submerged Implant System	Angulated Abutment for INNO SLA Submerged Implant System	
Manufacturer	Cowellmedi Co., Ltd.	Cowellmedi Co., Ltd.	
Indications for Use	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	same
Appearance			same
Diameter	4.5, 4.8, 5.5mm	4.8mm	added small and large diameter
Post Height	5, 8mm	3.9, 4.9, 5.9, 6.9mm	added long height
Gingival Height	1, 2, 3, 4mm	1, 2, 3, 4mm	same
Connection Interface	Hex, Non-Hex	Hex, Non-Hex	same
Surface treatment	TiN Coating	TiN Coating	same
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	same
Angulation	15°, 25°	15°, 25°	same
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	same
Principle of operation	This component is placed into dental implants to provide support for prosthetic restorations. It is for permanent screw-retained abutment.	This component is placed into dental implants to provide support for prosthetic restorations. It is for permanent screw-retained abutment.	same
Substantial Equivalence Discussion			
The subject device has the same intended use, material, surface treatment, and design as the predicate device. This 510k is to add some more size options for diameter and post height. The wider range is to meet each patient needs and the difference is minor. Also the additional size was verified by performance test.			

- **Temporary Abutment**

	Subject Device	Predicate Device	Remark
510(k) Number	K201323	K132242	
Device Name	Temporary Abutment for INNO SLA Submerged Implant System	Temporary Abutment for INNO SLA Submerged Implant System	
Manufacturer	Cowellmedi Co., Ltd.	Cowellmedi Co., Ltd.	
Indications for Use	The INNO SLA Submerged Implant System is indicated for use in	The INNO SLA Submerged Implant System is indicated for use in	same

	partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	
Appearance			same
Diameter	4.5mm	4.8mm	added small diameter
Post Height	10mm	3.9, 4.9, 5.9, 6.9mm	added long height
Gingival Height	1mm	1, 2, 3, 4mm	same
Connection Interface	Hex, Non-Hex	Hex, Non-Hex	same
Surface treatment	N/A	N/A	same
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	same
Angulation	0°	0°	same
Material	Ti-6Al-4V ELI,	Ti-6Al-4V ELI	same
Principle of operation	This component is a provisional restoration intended for use with root-form endosseous dental implants to aid in prosthetic rehabilitation or provisional crown that aids in creating an esthetic emergence through the gingiva during the final prosthetic production.	This component is a provisional restoration intended for use with root-form endosseous dental implants to aid in prosthetic rehabilitation or provisional crown that aids in creating an esthetic emergence through the gingiva during the final prosthetic production.	same
Substantial Equivalence Discussion			
The subject device has the same intended use, material, surface treatment, and design as the predicate device. This 510k is to add some more size options for diameter and post height. The wider range is to meet each patient needs and the difference is minor.			

- **Sonator Abutment**

	Subject Device	Predicate Device	Remark
510(k) Number	K201323	K072878	
Device Name	Sonator Abutment for INNO SLA Submerged Implant System	Locator Implant Anchor Abutment for Endosseous Dental Implant	
Manufacturer	Cowellmedi Co., Ltd.	Zest Anchors, Inc.	
Indications for Use	The INNO SLA Submerged Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	The LOCATOR Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.	similar

Appearance			similar
Diameter	3.87, 4.5mm	3.25 to 6.5mm	same
Gingival Height	1, 1.5, 2, 3, 4, 5, 6mm	1, 2, 3, 4, 5, 6 mm	same
Connection Interface	Hex, Non-hex	Conical, External Hex, Internal Hex, Internal Multi Lobe	similar
Surface treatment	TiN Coating	TiN Coating	same
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	same
Angulation	0, 15°	0°, 10°, 20°	same
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	same
Principle of operation	This component is used for implant-retained muscosa-supported restorations, such as dentures. It supports implant retained mucoss supported over dentures.	This component is used for implant-retained muscosa-supported restorations, such as dentures. It supports implant retained mucoss supported over dentures.	similar
Substantial Equivalence Discussion			
The subject device has the same intended use, material, surface treatment, and design as the predicate device. The wording of the indications for use is different but the overall claims are the same between the devices. The wording of the subject device is more specific. The size range of the predicate device encompasses that of the subject device, so it does not raise an issue in performance or safety.			

8. Non-Clinical Testing

- Surface Modification: The TiN coating for the subject abutments has the same specifications and processes as the predicate device cleared under K132242. The surface modification information for the TiN coating as recommended in the FDA Guidance, "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" was provided in K132242 and leveraged for the subject devices.
- Cytotoxicity Testing provided on representative abutments with TiN coating as cleared under K132242 with the same raw materials and manufacturing processes as the subject devices. Cytotoxicity testing was performed according to ANSI/AAMI/ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity, and ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.
- Mechanical performance testing of the subject device was performed according to ISO 14801. The worst-case scenario was chosen based on the FDA Guidance, "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." The fatigue limit data demonstrated that constructs of the subject device abutments in combination with the stated compatible implants and used according to the proposed labeling, have sufficient strength for their intended use and are substantially equivalent to predicate devices with regard to mechanical performance.
- End-user sterility validation was conducted according to ISO 17665-1 and ISO 17665-2 for the prior clearance K132242 and leveraged for the subject devices.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the INNO SLA Submerged Implant System has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate similar design,
* incorporate the same material and the sterilization method

Based on the similarities, we conclude that the INNO Sub Implant System is substantially equivalent to the predicate devices.