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

December 27, 2024

Re: K241127
Trade/Device Name: INNO SLA Mini Plus® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 14, 2024
Received: December 3, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241127

Device Name
INNO SLA Mini Plus® Implant System

Indications for Use *(Describe)*
The INNO SLA Mini Plus® Implant System is divided into two types:

- Cemented Type
The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing stage of permanent endosseous dental implant, such as artificial teeth, in order to restore masticating function in partially edentulous patients.

- Ball Type
The Ball type is designed for use in dental implant surgery. The Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. The use of the Ball type implants is not to exceed one hundred and eighty (180) days.

The Cemented Type and Ball Type implant bodies are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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

(K241127)

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

Date: Dec 26, 2024

1. Applicant / Submitter:

Cowellmedi Co., Ltd.
48, Hakgam-daero 221beon-gil,
Sasang-gu, Busan,
46986, Republic of Korea
Tel. + 82-51-314-2028

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine CA 92612
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Subject Device:

Proprietary Name:	INNO SLA Mini Plus® Implant System
Common Name:	Endosseous dental implant
Device Classification:	II
Regulation Number:	21 CFR 872.3640
Device Name:	Implant, Endosseous, Root-Form
Classification Product Code:	DZE, NHA

4. Predicate Devices:

- Primary Predicate: S-Mini Implant System (K112540) by Neobiotech Co., Ltd.
- Reference Device: AnyOne Onestage Implant System (K210161) by MegaGen Implant Co., Ltd.
- Reference Device: The LOCATOR R-Tx® Attachment (K200827) System by Zest Anchors, LLC
- Reference Device: INNO SLA Submerged Implant System (K201323) by Cowellmedi Co., Ltd.
- Reference Device: INNO SLA Submerged Implant System (K132242) by Cowellmedi Co., Ltd.
- Reference Device: MS System (K083067) by Osstem Implant Co., Ltd.

5. Device Description:

The INNO SLA Mini Plus® Implant System has two types, cement type and ball type.
The INNO SLA Mini Plus® Implant System is a one-piece endosseous dental implant which is a combination of implant and abutment sections. The implant is made of commercially pure titanium and has S.L.A. surface treatment.

6. Indications for Use:

The INNO SLA Mini Plus® Implant System is divided into two types:

- Cemented Type
The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing stage of permanent endosseous dental implant, such as artificial teeth, in order to restore masticating function in partially edentulous patients.

- Ball Type
The Ball type is designed for use in dental implant surgery. The Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. The use of the Ball type implants is not to exceed one hundred and eighty (180) days.

The Cemented Type and Ball Type implant bodies are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

7. Substantial Equivalence

Substantial Equivalence Discussion

The Cement Type of INNO SLA Mini Plus® Implant System has the same device characteristics as the predicate device, S-Mini Implant System (K112540) by Neobiotech Co., Ltd. and MS System (K083067) by Osstem Implant Co., Ltd. in terms of intended use, design and use concept. The size range of the predicate device and the reference devices encompasses the subject device.

Same for the Ball Type, the INNO SLA Mini Plus® Implant System has the same device characteristics as the predicate device, S-Mini Implant System (K112540) by Neobiotech Co., Ltd in terms of intended use, design and use concept. The size range of the predicate device encompasses the subject device.

For the implants, the difference is the surface treatment; however, the biocompatibility and chemical analysis were performed and the test results support substantial equivalence.

The subject cap and ball attachments have the same intended use, design, raw material, and the technical characteristics as the predicate device. We performed the biocompatibility test and determine the subject components does not raise a question in substantial equivalence.

Lastly, we presented two references devices which are made by our company to be leveraged for biocompatibility and shelf life tests.

Based on the information and test results provided in submission, we conclude that the subject device is substantially equivalent to the predicate device.

Comparison Chart

7.1. Mini Plus Fixture – Cement Type

	Subject Device	Predicate Device	Reference Device
510(k) Number	K232104	K112540	K083067
Device Name	**Mini Plus Fixture - Cement Type** INNO SLA Mini Plus® Implant System	S-Mini Implant System	MS System
Manufacturer	Cowellmedi Co., Ltd.	Neobiotech Co., Ltd.	Osstem Implant Co., Ltd.
Intended Use	The INNO SLA Mini Plus® Implant System is divided into two types: - Cemented Type The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing stage of permanent endosseous dental implant, such as artificial teeth, in order to restore masticating function in partially edentulous patients. The Cemented Type implant bodies are indicated for immediate loading when good primary stability is achieved and with	The Cemented type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing phase of permanent endosseous dental implant, such as artificial teeth, in order to restore chewing function in partially edentulous patients.	The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) is intended for single use only. It is not for immediate loading.

	appropriate occlusal loading.		
Design			
Diameters(Ø)	2.5/3.0	2.0/2.5/3.0/3.5	3.0
Lengths(mm)	10.0/12.0/14.0	7.0/8.5/10.0/11.5/13.0/15.0	10.0/13.0/15.0
Gingival heights/cuffs(mm)	2.0/4.0	2.0	2.5/4.0
Product Code	DZE	DZE	DZE
Regulation	872.3640	872.3640	872.3640
Surface treatment	SLA	RBM	RBM
Sterility	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Angulation	0°	0°	0°
Material	CP Ti Gr.4	CP Ti Gr.4	Ti 6Al 4V ELI
Principle of operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.

7.2. Mini Plus Fixture - Ball Type

	Subject Device	Predicate Device
510(k) Number	K232104	K112540
Device Name	**Mini Plus Fixture - Ball Type** INNO SLA Mini Plus® Implant System	S-Mini Implant System
Manufacturer	Cowellmedi Co., Ltd.	Neobiotech Co., Ltd
Intended Use	The INNO SLA Mini Plus® Implant System is divided into two types: - Ball Type The Ball type is designed for use in dental implant surgery. The Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. The use of the Ball type implants is not to exceed one hundred and eighty (180) days. The Ball Type implant bodies are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Ball type is designed for use in dental implant surgery. Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. Ball type implants are for temporary use only.
Design		
Diameters(Ø)	2.5/3.0	2.0/2.5/3.0/3.5
Lengths(mm)	10.0/12.0/14.0	7.0/8.5/10.0/11.5/13.0/15.0
Gingival heights/cuffs	2.0/4.0	3.0/4.0
Product Code	DZE	DZE
Regulation	872.3640	872.3640
Surface treatment	SLA	RBM
Sterility	Gamma Sterilization	Gamma Sterilization
Angulation	0°	0°
Material	CP Ti Gr.4	CP Ti Gr.4
Principle of operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.

7.3. Protection Cap

	Subject Device	Predicate Device
510(k) Number	K232104	K210161
Device Name	**Protection Cap** INNO SLA Mini Plus® Implant System	**Solid Post Cap** For AnyOne Onestage Implant System
Manufacturer	Cowellmedi Co., Ltd.	MegaGen Implant Co., Ltd.
Intended Use	The INNO SLA Mini Plus® Implant System is divided into two types: - Cemented Type The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing stage of permanent endosseous dental implant, such as artificial teeth, in order to restore masticating function in partially edentulous patients. - Ball Type The Ball type is designed for use in dental implant surgery. The Ball type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. The use of the Ball type implants is not to exceed one hundred and eighty (180) days. The Cemented Type and Ball Type implant bodies are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The AnyOne Onestage Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.

Design		
Diameters(Ø)	4.05 mm	5.3 mm
Lengths(mm)	6.8 mm	6.5, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0, 10.5, 11.5 mm
Regulation	872.3640	872.3640
Sterility	Steam Sterilization	Steam Sterilization
Single Use	Yes	Yes
Material	POM	POM
Principle of operation	The Protection Cap is used for protecting a MiniPlus cemented type fixture, and minimizing irritation to tongue, gingiva and oral mucosa.	The Solid Post Cap is used for protecting a Solid Post Abutment after taking impression, and minimizing irritation to tongue and oral mucosa.

7.4. Ball Attachment (Ball outer Cap, Ball Inner Cap)

	Subject Device	Predicate Device
510(k) Number	K232104	K200827
Device Name	**Ball outer cap, Ball Inner cap** INNO SLA Mini Plus® Implant System	The LOCATOR R-Tx® Attachment System
Manufacturer	Cowellmedi Co., Ltd.	Zest Anchors, LLC
Intended Use	The INNO SLA Mini Plus® Implant System is divided into two types: - Cemented Type The Cement type is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to serve as temporary support prosthetic devices during the healing stage of permanent endosseous dental implant, such as artificial teeth, in order to restore masticating function in partially edentulous patients. - Ball Type The Ball type is designed for use in dental implant surgery. The Ball	The LOCATOR R-Tx® Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.

		type is intended for use in partially or fully edentulous mandibles and maxillae, in support of overdentures. The use of the Ball type implants is not to exceed one hundred and eighty (180) days. The Cemented Type and Ball Type implant bodies are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	
Design	Abutment Diameter (mm)	3.4	2.75 – 6.0
	Abutment Angle	Straight	Straight
Material	Abutment	 Ti-6A1-4V ELI	Ti-6Al-4V ELI
	Prosthetic Retention Component	 Nylon	Nylon or Peek
Product Code		NHA	NHA
Regulation		872.3630	872.3630
Principle of operation		Abutment design that connects to a housing embedded in a denture ridge, which nylon inserts are used to allow connection and disconnection of the denture to the abutment for "removable" denture solution for the patient	Abutment design that connects to a housing embedded in a denture ridge, which nylon inserts are used to allow connection and disconnection of the denture to the abutment for "removable" denture solution for the patient

8. Performance Data (Non-Clinical):

- Leveraged K201323 for sterilization validating and biocompatibility tests
- Leveraged K132242 for shelf life test and SLA surface treatment analysis
- Sterilization validation test for POM caps and Nylon caps in accordance with ISO 17665-1 and ISO 17665-2
- The endotoxin testing will be conducted on a random batch every two months for the subject device. The test method to verify pyrogen limit specifications will be the Limulus amebocyte lysate (LAL) test. We are planning to apply gel-clot technique (limit test and assay method) among currently three commonly accepted BET techniques (ANSI/AAMI ST72:2011, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing. Annex B).
- Fatigue testing was not required as there are no angled abutments in the subject submission.

- MRI Safety
  A non-clinical worst-case MRI review was conducted to evaluate the INNO SLA Mini Plus® Implant System in an MRI environment. Various dental journals were utilized to ensure its stability, and scientific evidence from literature was considered, such as the study by Yong-Ha Kim, Manki Choi, and Jae-Won Kim titled 'Are titanium implants actually safe for magnetic resonance imaging examinations?' (Arch Plast Surg 2019;46:96-97). The study concluded that titanium, being a paramagnetic material, is not affected by the magnetic field of MRI. The risk of implant-based complications is very low, and MRI can be safely used in patients with implants. Based on this paper, the stability of the raw material of the INNO SLA Mini Plus® Implant System in an MRI environment was confirmed.

  In the study conducted by Woods, Terry O., Jana G. Delfino, and Sunder Rajan titled "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), Titanium Grade 4 was evaluated using magnetic induction displacement force (ASTM F2052), magnetic induction torque (ASTM F2213), RF induction heating (ASTM F2182), and image artifact (ASTM F2119) tests by T. O. Woods et al. Based on this research, we have addressed parameters per FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment".

9. Conclusion:

Based on the information provided herein, Cowellmedi Co., Ltd. concludes that the INNO SLA Mini Plus® Implant System is substantially equivalent to the predicate.