October 18, 2023

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

Re: K231395
Trade/Device Name: INNO SLA Submerged Narrow Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 18, 2023
Received: September 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)*
K231395

Device Name
INNO SLA Submerged Narrow Implant System

Indications for Use *(Describe)*
INNO SLA Submerged Narrow Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:
- The intended use for the 3.3mm, 3.5mm diameter INNO Sub Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed 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.

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510(k) Summary

(k231395)

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

Date: ___Oct 18, 2023___

1. Applicant / Submitter:

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46986, Republic of Korea
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2. Submission Correspondent:

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3. Device:

Proprietary Name:	INNO SLA Submerged Narrow Implant System
Common Name:	Endosseous dental implant
Classification Name:	Implant, Endosseous, Root-Form
Classification:	Class II, 21 CFR 872.3640
Classification Product Code:	DZE, NHA

4. Predicate Device:

- Primary Predicate Device: UF(II) Narrow Implant System (K161987) by Dio, Inc.
- Reference Device:
  - Straumann® Ø2.9 mm Bone Level Tapered Implants (K162890) by Straumann USA, LLC
  - Healing Abutment for INNO SLA Submerged Implant System (K132242) by Cowellmedi Co., Ltd.

- Angulated Abutment for INNO SLA Submerged Implant System (K201323) by Cowellmedi Co., Ltd.
- IS-III active System (K181138) by Neobiotech Co., Ltd.
- Paltop Narrow Implant (K210117) by Paltop Advanced Dental Solutions, Ltd
- Superline (K160965) by Dentium Co., Ltd.
- Oneplant Dental Implant System (K081748) by WARANTEC Implant Co., Ltd.
- URIS OMNI Narrow System & Prosthetic (K200817) by TruAbutment Korea Co., Ltd.
- Magicore Solid Abutment (K201981) by InnoBioSurg Co., Ltd.
- Multi Unit Temporary Cylinder (K210903) by Neobiotech Co., Ltd
- BTI Interna Narrow/Plus Dental Implant System UnicCa (K211952) by B.T.I. Biotechnology Institute, SL

5. Device Description:

The INNO SLA Submerged Implant System offers the following components.

No	Component
1	INNO SLA Submerged Narrow Fixture (Narrow) Ø 3.3 x 8.00, 10.00, 12.00, 14.00 mm Ø 3.5 x 8.00, 10.00, 12.00, 14.00 mm
2	Cover Screw (Narrow) Ø 2.84 x 5.0 mm Ø 3.23 x 6.0 mm Ø 3.62 x 7.0 mm
3	Healing Abutment (Narrow) Type 1 Ø3.5 x 6.7, 7.2, 9.2, 10.2, 11.2 mm
4	Healing Abutment (Narrow) Type 2 Ø 4.5 x 7, 9, 10, 11, 12, 14 mm
5	Cemented Abutment (Narrow) Ø 4.5 x 7.85, 8.85, 9.85, 10.85, 11.85, 12.85, 13.85, 14.85mm Ø 4.5 x 9.35, 10.35, 11.35, 12.35, 13.35 mm Ø 4.5 x 7.65, 8.65, 9.65, 10.65, 11.65, 13.65, 14.65 mm Ø 4.5 x 9.15, 10.15, 11.15, 12.15, 13.15 mm
6	Angulated Abutment (Narrow) Ø 4.5 x 11.85, 12.85, 13.85, 14.85 mm (15°, 25°)
7	Multi S Abutment Ø 4.5 x 5, 5.8, 6mm
8	Multi A Abutment Ø 4.5 x 6.42, 7.42, 8.42, 6.96, 7.96mm (15,30°) – Hex type Ø 4.5 x 6.23, 7.22, 8.22, 6.76, 7.76mm (15,30°) – Non Hex type
9	Multi Hybrid Ti-Base Cylinder Ø 4.5 x 4.5mm
10	Abutment Screw (Narrow) Ø 2.25 x 10.2 mm Ø 1.95 x 8.7 mm

	Ø 1.95 x 9.3 mm
12	Multi Cylinder Screw Ø 2.25 x 5 mm
13	Straight Abutment Ø 3.5 x 13.5, 14, 15, 16, 17 mm
14	Temporary Abutment Ø 4.5 x 10 mm
15	Multi Titanium Cylinder Ø 4.5 x 9 mm

6. Indications for Use:

INNO SLA Submerged Narrow Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:
- The intended use for the 3.3mm, 3.5mm diameter INNO Sub Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors.
- Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.
- It is intended for delayed loading.

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.

- Cowellmedi Co., Ltd.'s own clearance K132242 was leveraged for the gamma radiation sterilization, and shelf-life of the dental implants, and K201323 was leveraged for the steam sterilization of the abutments.
- Five-year shelf life and packaging were leveraged from Cowellmedi Co., Ltd's own previous clearance K132242.
- Cowellmedi Co., Ltd.'s own previous clearance K132242 was leveraged for the SLA surface treatment.
- Fatigue test in accordance with ISO 14801
- The biocompatibility endpoints were leveraged from the Cowellmedi Co., Ltd.'s own previous clearance K132242
- Non-clinical worst-case MRI review was performed to evaluate the subject device components 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, 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

Substantial Equivalence Discussion

The INNO SLA Submerged Narrow 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

- **Fixture**

	Subject Device	Predicate Device	Reference Device
510(k) Number	k231395	K161987	K211952
Device Name	INNO SLA Submerged Narrow Implant System - Fixture	UF(II) Narrow Implant System	BTI Interna Narrow/Plus Dental Implant System UnicCa ®
Manufacturer	Cowellmedi Co., Ltd.	Dio	B.T.I. Biotechnology Institute, SL.
Indications for Use	The INNO SLA Submerged Narrow Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: -The intended use for the 3.3mm, 3.5mm diameter Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. -It is intended for delayed loading.	The UF(II) Narrow Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: -The intended use for the 3.0mm, 3.3mm diameter UF(II) Narrow Implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. -It is intended for delayed loading.	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. Tiny® 3.0 UnicCa® implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

Design			
Diameter	3.3. 3.5 mm	3.0, 3.3mm	3.3/3.5/3.75/4.0/4.25/4.75
Lengths(mm)	8, 10, 12, 14mm	8.5, 10, 11.5, 13, 15mm	5.5/6.5/7.5/8.5/10/11.5/13/15
Connection Interface	Internal Hex	Internal Hex	Internal Hex Non - Submerged
Surface treatment	SLA	SLA	Calcium surface treatment
Sterility	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization
Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 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.	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.
Shelf Life	5 years	5 years	5 years
Substantial Equivalence Discussion			
The subject device has the same intended use, material, principle of operation, and design as the predicate devices. We identified a reference device (K211952) which covers the fixture size range of the subject device.			

- **Healing Abutment (Type 1)**

	Subject Device	Predicate Device
510(k) Number	k231395	K162890
Device Name	Healing Abutment for INNO SLA Submerged Narrow Implant System	Straumann® Ø2.9 mm Bone Level Tapered Implants
Manufacturer	Cowellmedi Co., Ltd.	Straumann USA, LLC
Appearance		
Diameter	3.5 mm	Closure Cap: Ø2.4 mm Healing Abutments: 3.3/4.3 mm 3.55/4.86 mm 3.6/5.0 mm
Post Height	1, 2mm	-
Gingival Height	0.5, 1, 2, 3, 4mm	Closure Cap: 0.5 mm Healing Abutments: 2.0, 3.5, 5.0 and 6.5 mm
Connection Interface	Hex, Non-hex	-
Surface treatment	N/A	N/A
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	The intended use is to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.	The intended use is to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

Substantial Equivalence Discussion
The subject device has the same intended use, material, and principle of operation as the predicate device. The design is slightly different but that does not raise a question in safety or performance.

- **Healing Abutment (Type 2)**

	Subject Device	Predicate Device
510(k) Number	k231395	K132242
Device Name	Healing Abutment for INNO SLA Submerged Narrow Implant System	Healing Abutment for INNO SLA Submerged Implant System
Manufacturer	Cowellmedi Co., Ltd.	Cowellmedi Co., Ltd.
Appearance		
Diameter	4.5 mm	4.1, 4.5, 4.9, 5.5, 5.95, 6.5mm
Post Height	1, 2mm	2, 3, 4, 5, 6, 7, 9mm
Gingival Height	1, 2, 3, 4, 5, 7mm	1, 2, 3, 4, 5, 7mm
Connection Interface	Hex, Non-hex	Hex, Non-hex
Surface treatment	N/A	N/A
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion
The subject device has the same intended use, material, principle of operation, and design as the predicate device. The wider range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is minor.

- **Angulated Abutment**

	Subject Device	Predicate Device
510(k) Number	k231395	K201323
Device Name	Angulated Abutment for INNO SLA Submerged Narrow Implant System	Angulated Abutment for INNO SLA Submerged Implant System
Manufacturer	Cowellmedi Co., Ltd.	Cowellmedi Co., Ltd.
Appearance		
Diameter	4.5mm	4.5mm
Post Height	8mm	5, 8mm
Gingival Height	1, 2, 3, 4mm	1, 2, 3, 4mm
Connection Interface	Hex, Non-Hex	Hex, Non-Hex
Surface treatment	TiN Coating	TiN Coating
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	15°, 25°	15°, 25°
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures. It replaces the	This product is a superstructure which is connects with the fixtures using the

	functions of the missing teeth as a dental abutment.	Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion
The subject device has the same intended use, material, principle of operation, surface treatment, and design as the predicate device. The size range of the predicate device encompasses that of the subject device.

- **Cemented Abutment**

	Subject Device	Predicate Device
510(k) Number	k231395	K181138
Device Name	Cemented Abutment for INNO SLA Submerged Narrow Implant System	IS-III active System
Manufacturer	Cowellmedi Co., Ltd.	Neobiotech Co., Ltd
Appearance		
Diameter	4.5mm	4.5/5.2/5.7/6.5mm
Post	4/5.5/7mm	4.0/4.5/5.5/7.0/8.0mm
Connection Interface	Hex, Non-Hex	Hex, Non-Hex
Surface treatment	TiN Coating	TiN Coating
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.

Substantial Equivalence Discussion
The subject device has the same intended use, material, principle of operation, surface treatment, and design as the predicate device. The size range of the predicate device encompasses that of the subject device.

- **Multi S Abutment**

	Subject Device	Predicate Device
510(k) Number	k231395	K210117
Device Name	Multi S Abutment for INNO SLA Submerged Narrow Implant System	Paltop Narrow Implant
Manufacturer	Cowellmedi Co., Ltd.	Paltop Advanced Dental Solutions, Ltd
Appearance		
Diameter	4.5mm	4.5mm
G/H	1/2/3/4/5mm	1/2/3/4/5mm

Connection Interface	Hex	Hex
Surface treatment	TiN Coating	-
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.

Substantial Equivalence Discussion
The subject device (Multi S Abutment) is substantially equivalent to the predicate device (Multi Abutment, K161689). The subject device and the predicate device have the same internal implant interface connections, are made of Ti-6Al-4V ELI. There is a slight difference in surface treatment, but it does not raise a concern in safety or effectiveness based on our biocompatibility evaluations.

- **Multi A Abutment**

	Subject Device	Predicate Device
510(k) Number		K160965
Device Name	Multi A Abutment for INNO SLA Submerged Narrow Implant System	Superline
Manufacturer	Cowellmedi Co., Ltd.	Dentium Co., Ltd
Appearance		
Diameter	4.5mm	4.5mm
G/H	2,3,4mm	1/1.5/2/2.5/3/3.5/4/4.5/5/5.5mm
Interface abutment-implant	Internal	Internal
Surface treatment	TiN Coating	Tin Coating
Sterility	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	15°, 30°	15°,20°, 30°
Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.	It is indicated for screw-retained single tooth or cement retained single tooth and bridge restorations.
Substantial Equivalence Discussion		
The subject device (Multi A Abutment) is substantially equivalent to the predicate device. The subject device and the predicate device have the same internal implant interface connections, are made of Ti-6Al-4V ELI. The size of the predicate device encompasses that of the subject device.		

- **Multi Hybrid Ti Cylinder**

	Subject Device	Predicate Device
510(k) Number	k231395	K081748
Device Name	Multi Hybrid Ti Cylinder	Oneplant Dental Implant System
Manufacturer	Cowellmedi Co., Ltd.	WARANTEC Implant Co., Ltd
Appearance		
Diameter	4.5mm	Hex/Non-Hex: 4.5/5.5mm
Post	4.5mm	-
Sterility	End User Sterilization	End User Sterilization
Material	Ti-6Al-4V ELI	Titanium Alloy
Principle of operation	Multi Hybrid Ti Cylinder is intended for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.	ONEPLANT is designed for use in dental implant surgery. These are intended for use in partially or fully edentulous mandibles and maxillae to support for single or multiple-unit restorations such as cemented retained, or over denture restorations and terminal or intermediate abutment support for fixed bridgework.

Substantial Equivalence Discussion
The subject device has the same intended use, material, principle of operation, and similar design as the predicate device.

- **Multi Cylinder Screw**

	Subject Device	Predicate Device
510(k) Number	k231395	K200817
Device Name	Multi Cylinder Screw	URIS OMNI Narrow System & Prosthetic
Manufacturer	Cowellmedi Co., Ltd.	TruAbutment Korea Co., Ltd
Appearance		
Diameter	2.25mm	1.6mm
Length	5mm	3.3 mm
Sterility	End User Sterilization	End User Sterilization
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Principle of operation	Multi-unit Cylinder Screw is a premanufactured prosthetic component directly connected to the endosseous dental	Multi-unit Cylinder Screw is a premanufactured prosthetic component directly connected to the endosseous dental

	implant and is intended for use as an aid in prosthetic rehabilitation.	implant and is intended for use as an aid in prosthetic rehabilitation.

Substantial Equivalence Discussion
The subject device has the same intended use, material, principle of operation, and design as the predicate device. There is a slight difference in size, but it does not raise a concern in safety or effectiveness.

- **Straight Abutment**

	Subject Device	Predicate Device
510(k) Number	k231395	K201981
Device Name	Straight Abutment	Magicore Solid Abutment
Manufacturer	Cowellmedi Co., Ltd.	InnoBioSurg Co., Ltd.
Appearance		
Diameter	3.5mm	3.5/3.86/4.3/4.6mm
Post	8mm	7.6/8.6/9.6/10.6/11.6 mm
Sterility	End User Sterilization	End User Sterilization
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Principle of operation	Straight Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Straight Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

Substantial Equivalence Discussion
The subject device has the same intended use, material, principle of operation, and similar design as the predicate device. The size range of the predicate device encompasses that of the subject device.

- **Temporary Abutment**

	Subject Device	Predicate Device
510(k) Number	k231395	K181138
Device Name	Temporary Abutment	IS-III active System
Manufacturer	Cowellmedi Co., Ltd.	Neobiotech Co., Ltd
Appearance		
Diameter	4.5mm	4.5mm
Post	10mm	6.0/8.0/11.5 mm
Sterility	End User Sterilization	End User Sterilization
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Principle of operation	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.	It is dental Abutments designed to serve as a temporary dental prosthesis during the healing process until a permanent crown is made.

Substantial Equivalence Discussion

The subject device has the same intended use, material, principle of operation, and similar design as the predicate device. The size range of the predicate device encompasses that of the subject device.

- **Multi Titanium Cylinder**

	Subject Device	1st Predicate Device	2nd Predicate Device
510(k) Number	k231395	K210117	K210903
Device Name	Multi Titanium Cylinder	Multi-Unit Cylinder	Multi Unit Temporary Cylinder
Manufacturer	Cowellmedi Co., Ltd.	Paltop Advanced Dental Solutions, Ltd	Neobiotech Co., Ltd
Appearance			
Diameter	4.5mm	4.5mm	4.8/6.0mm
Post	9mm	-	11mm
Angle	0°	0°	0°
Sterility	End User Sterilization	End User Sterilization	End User Sterilization
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Principle of operation	Multi Titanium Cylinder is designed to serve as a temporary dental prosthesis during the healing process until a permanent bridges are made.	-	It is designed to serve as a temporary dental prosthesis during the healing process until a permanent bridges are made.
Duration of Use	90 days	-	90 days
Substantial Equivalence Discussion			
The subject device has the same diameter size as the first predicate device. The subject device has the same intended use, material, principle of operation, and similar design as the second predicate device.			

9. Conclusion:

Based on the testing results, Cowellmedi Co., Ltd. concludes that the INNO SLA Submerged Narrow Implant System is substantially equivalent to the predicate devices.