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

November 21, 2023

Re: K232546
Trade/Device Name: Meta G UCLA Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 26, 2023
Received: August 24, 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)*

K232546

Device Name

Meta G UCLA Abutment

Indications for Use *(Describe)*

Meta G UCLA Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

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

(K232546)

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

Date: ___November 16, 2023___

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	Meta G UCLA Abutment
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Classification:	Class II, 21 CFR 872.3630
Classification Product Code:	NHA

4. Predicate and Reference Devices:

- Primary Predicate Device: UCLA CCM Abutment (K192263) by DIO Corporation
- 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: INNO SLA Submerged Narrow Implant System (K231395) by Cowellmedi Co., Ltd.

5. Device Description:

The Meta G UCLA Abutment is used for prosthetic restoration. The Meta G UCLA Abutment consists of Meta G UCLA Abutment and abutment screws. The Meta G UCLA Abutment is made of CCM (ASTM F1537) and POM (ASTM F1855). The casting material to make prosthesis is also CCM. When cast a prosthesis with the Meta G UCLA Abutment, the post height above the transmucosal collar of the Meta G UCLA Abutment has to be taller than 4mm and maximum 7mm.
The Meta G UCLA Abutment has Hex, Non Hex connection. Hex-type abutment should be used for single unit restorations and is not recommended for multiple tooth restorations. Non Hex-type abutment is for multiunit restorations only. No angulation is to be incorporated into the cast final device and abutments should not be used on implants placed at an angle.
It is provided non-sterile, this should be user steam sterilized before use.
The Meta G UCLA abutment is compatible with our own implant system.

- INNO SLA Submerged Implant System(K132242) by Cowellmedi Co., Ltd.
- INNO SLA Submerged Narrow Implant System (K231395) by Cowellmedi Co., Ltd.

The design envelope for the Meta G UCLA Abutment is as follows.

<Design limits – Meta G UCLA Abutment>
Minimum Diameter: 4.5 mm (0.18 in)
Minimum Thickness : 0.8mm
Maximum Total Cuff Height : 4mm
Minimum Total Cuff Height : 1mm
Maximum Cuff Height of Casting CCM part : 3mm
Minimum Cuff Height of Casting CCM part : 0mm
Post height: minimum of 4mm and maximum of 7mm

<Design limits – Meta G UCLA Abutment (Narrow)>
Minimum Diameter: 4.5 mm (0.18 in)
Minimum Thickness : 0.93mm
Maximum Total Cuff Height : 4mm
Minimum Total Cuff Height : 1mm
Maximum Cuff Height of Casting CCM part : 3mm
Minimum Cuff Height of Casting CCM part : 0mm
Post height: minimum of 4mm and maximum of 7mm

6. Indications for Use:

Meta G UCLA Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device or previously provided in a reference 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 for the subject device has been performed in accordance with ISO 10993-3, 5, 10, 11.
- Biocompatibility of the abutment screw (Ti-6Al-4V) was included in a previously cleared submission identified as reference device (K201323).
- MR Environment Condition
  Non-clinical worst-case MRI review was performed to evaluate the metallic Meta G UCLA abutment 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

8.1. Comparison Chart

	Subject Device	Predicate Device
510(K) No.	K232546	K192263
Applicant	Cowellmedi Co., Ltd.	DIO Corporation
Trade Name	Meta G UCLA Abutment	UCLA CCM Abutment
Classification Name	Endosseous Dental Implant Abutment (872.3630)	Endosseous Dental Implant Abutment (872.3630)
Product Code	NHA	NHA
Class	II	II
Material	CCM & POM	CCM & POM
Indications For Use/ Intended Use	Meta G UCLA Abutment is intended for use with a dental implant to provide	UCLA CCM Abutment is intended for use with a dental implant to provide support for

	Subject Device	Predicate Device
	support for prosthetic restorations such as crowns, bridges, or overdentures.	prosthetic restorations such as crowns, bridges, or overdentures.
Design Limits		
Diameters (mm)	4.5	4.0 / 4.5
Cuff (mm)	1, 2, 3 mm	1, 3 mm
Angulation	0°	0°
Sterile	Non-sterile	Non-sterile

8.2. Substantial Equivalence Discussion

Meta G UCLA Abutment is substantially equivalent in indications for use, material, dimension, sterilization and similar design, technological characteristics as primary predicate device (K192263). The only difference is in design, but it is very minor and does not raise new questions.
We identified refence devices (K132242 & K231395) which is used with the subject device, and another device (K201323) to leverage biocompatibility testing.

Based on the information provided herein, we determine that the subject device is substantially equivalent to the predicate device.

9. Conclusion:

Based on the testing result and a comparison of technological characteristics, Cowellmedi Co., Ltd. concludes that the Meta G UCLA Abutment is substantially equivalent to the predicate device.