February 21, 2020

DIO Corporation
℅ Peter Kang
Business, Manager
DIO USA
3470 Wilshire Blvd, #620
Los Angeles, California 90010

Re: K192263
Trade/Device Name: UCLA CCM Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 21, 2020
Received: January 23, 2020

Dear Peter Kang:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K192263

Device Name
UCLA CCM Abutment

Indications for Use *(Describe)*
UCLA CCM 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

K 192263

This 510(k) Summary is being submitted in accordance with requirement of 21 CFR part 807.92

Submitter:
Jiae Park
DIO Corporation
66 Centum seo-ro, Haeundae-gu,
Busan, 48058, Republic of Korea
Phone +82-51-745-7836
Fax +82-51-745-7781

Contact / US agent:
Peter Kang
DIO USA.
3470 Wilshire Blvd. #620
Los Angeles, CA
Phone +1-213-365-2875
Fax +1-213-365-1595

Device Information:

Trade Name: UCLA CCM abutment
Classification Name: Endosseous dental implant abutment
Regulation Number: 21 CFR 872.3630
Product Code: NHA
Panel: Dental
Device Class: Class II
Date prepared: 02/21/2020

Indication For Use

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

Predicate devices

The subject device is substantially equivalent to the following Predicate Device:

Primary predicate : NP-Cast Abutment System (K121843)

Reference Devices : UV Active Implant System, CCM Cylinder (K182194)
DIO CAD/CAM Abutment (K181037)
UF(II) Narrow Implant System (K161987)
UF Submerged Implant System (K122519)
UF(II) Implant System (K170608)
UF(II) Wide Fixture (K173975)

General Description

UCLA CCM Abutment is used for prosthetic restoration. It is used for cases with path and aesthetic and spatial constrainsts. After customization, be sure to use only dental non-precious metal for casting to make the prosthesis. When cast a prosthesis with UCLA CCM Abutment, the post height above the transmucosal collar of UCLA CCM Abutment has to be taller than 4mm.

The subject device is not to be used with any angulation and are straight only.

UCLA CCM 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 multi-unit restorations only. Both abutments types are compatible with all compatible implant bodies (K182194,

K161987, K122519, K170608 and K173975)
UCLA CCM Abutments are made from CCM Alloy. UCLA CCM Abutment consists of UCLA CCM Abutment and abutment screw. It is provided non-sterile, this should be user steam sterilized before use.
The UCLA CCM abutment compatible following own predicate Implant system.

Proprietary Name	**UV Active Implant System**	**UF(II) Narrow Implant System**	**UF Sub merged Implant System**	**UF(II) Implant System**	**UF(II) Wide Fixture**
Compatible Implants (Knumber)	K182194	K161987	K122519	K170608	K173975
Implant diameter size(mm)	3.0/3.3/3.8/4.0/ 4.5/5.0/5.5/6.0/ 6.5	3.0/3.3	3.8/4.0/4.5/5.0/ 5.5/6.0/6.5/7.0	3.8/4.0/45/5.0/5 .5	5.9/6.4/6.9
Implant Interface Connection Type/Size(mm)	Internal connection type/2.3, 3.35	Internal connection type/2.3	Internal connection type/3.35	Internal connection type/3.35	Internal connection type/3.35
Type of Implant-Abutment Connection	Hex/Non Hex	Hex/Non Hex	Hex/Non Hex	Hex/Non Hex	Hex/Non Hex

Summaries of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

	Subject Devices		**Primary Devices**		**Reference Devices**	
Applicant	DIO Corporation		OSSTEM Implant Co., Ltd.		DIO Corporation	
Trade Name	UCLA CCM Abutment		NP-Cast Abutment System		UV Active Implant System CCM Cylinder	
510(K) No.	K192263		K121843		K182194	
Classification Name	Endosseous Dental Implant Abutments (872.3630)		Endosseous Dental Implant Abutments (872.3630)		Endosseous Dental Implant Abutments (872.3630)	
Product Code	NHA		NHA		NHA	
Class	II		II		II	
Material	**CCM Abutment**	CoCrMo Alloys	**CCM Abutment**	CoCrMo Alloys	**CCM Abutment**	CoCrMo Alloys
	Plastic Sleeve	POM	**Plastic Sleeve**	POM	**Plastic Sleeve**	POM
Design	**Hex**	**Non-Hex**	**Hex**	**Non-Hex**	**Hex**	**Non-Hex**
						
Diameters (mm)	4.0/4.5	4.0/4.5	4.0/4.5	4.0/4.5	5.0	5.0
Height (mm)	1.0/3.0	1.0/3.0	1.0/3.0	1.0/3.0	2.4	2.4

Maximum angulation	0°	30°	15°
Sterilization	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Delivered non sterile)
Indications For Use/ Intended Use	UCLA CCM Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The NP-Cast Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	CCM Cylinder 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. And it should be used with multi-unit abutment. It has Hex and Non-hex connection.
Substantial Equivalence Discussion	**Similarities :** UCLA CCM Abutment is substantially equivalent in indications for use, material, dimension, sterilization and similar design, technological characteristics as primary predicate device (K121843). UCLA CCM Abutment has same material, packaging, manufacturing process as own reference device (K182194). **Differences :** The subject device and reference devices are different in detailed shape, Indications for use and dimension. To support this discrepancy, primary predicate device(K121843) selected in this submission. The subject device's maximum angulation is different from primary predicate device (K121843). However, the subject device's maximum angulations are in the range of angulation of primary predicate device (K121843). The UCLA CCM Abutment is identical in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate device.		

Non-clinical Testing

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario. The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device.

Fatigue Testing

Since the design does not include any angulation, fatigue testing was not conducted.

Sterilization Validation and Shelf Life Testing

Sterilization validating testing has been performed in accordance with ISO 17665-1 and ISO 17665-2 for steam sterilization. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met. The subject device is leveraged sterilization validation from K181037.

For the subject devices provided non-sterile status.

Biocompatibility

The Biocompatibility Test are leveraged from own predicate device (K182194).
We provided the biocompatibility test report of the CoCrMo Alloys in own predicate device (K182194) per *the FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".*
CoCrMo Alloys used for the subject device and own predicate device (K182194) is exactly same from same manufacturer. The predicate device (K182194) support substantial equivalences because same manufacturing process and material are used for subject and own reference device. No new issues of biocompatibility are raised for the subject devices. Therefore, no additional biocompatibility testing was required.

Summary of clinical testing

No clinical testing was performed for this submission.

Conclusions

The UCLA CCM abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, UCLA CCM abutment sand its predicates are substantially equivalent.