December 3, 2020

InnoBioSurg Co., Ltd.
% April Lee
Consultant
Withus Group Inc.
106 Superior
Irvine, California 92620

Re: K202418
Trade/Device Name: Magic UCLA Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 3, 2020
Received: November 3, 2020

Dear April Lee:

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 Steen
Assistant 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)*
K202418

Device Name
Magic UCLA Abutment System

Indications for Use *(Describe)*
The Magic UCLA Abutment System is intended to replace missing teeth to restore chewing function. The Magic UCLA Abutment System can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Device Information

- Trade Name: Magic UCLA Abutment System
- Common Name: Dental Abutment System
- Classification Name: Endosseous dental implant abutment
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date prepared: 12/02/2020

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:

Primary Predicate
K173120, CCM Abutment System manufactured by InnoBioSurg Co., Ltd.

Reference Device
K153350, IBS Implant System manufactured by InnoBioSurg Co., Ltd.

General Description

The purpose of this submission is to add abutments to the previously cleared device, CCM Abutment System (K173120). The added abutments are below:

Abutments

- Magic UCLA Screw Retained Type (Hex, Non-Hex)
- Magic UCLA Cement Retained Type (Hex, Non-Hex)

The Magic UCLA Abutment System is used with a dental implant to provide support to prosthetic restorations such as crowns, bridges, and overdentures in partially or fully edentulous patients.

The subject device is compatible with the following implants:

K Number	Compatible Implant
K152520	Magicore System

The dimension ranges of the abutments are below:

Abutments	Diameter (mm)	Length (mm)
Magic UCLA Screw Retained Type	4.5	10.2
	5.2	10.4
	6.2	10.5
Magic UCLA Cement Retained Type	4.5	10.5
	5.2	11.1
	6.2	11.1

Tolerance of dimensions for Abutments shall be within ±1%.

The Magic UCLA Abutment System is provided non-sterile and packaged separately. The abutments should be sterilized before use. The Magic UCLA Screw Retained Type and the Magic UCLA Cement Retained Type are not intended to be cast at angulation or placed to provide angular correction.

Indications for Use

The Magic UCLA Abutment System is intended to replace missing teeth to restore chewing function. The Magic UCLA Abutment System can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.

Materials

Abutments are fabricated from Co-Cr-Mo Alloy with Poly Diacetate.

Summaries of Technological Characteristics:

Magic UCLA Screw Retained Type (Hex, Non-Hex)			
Device Name	**Subject Device**	**Primary Predicate Device**	**Reference Predicate Device**
	Magic UCLA Abutment System	CCM Abutment System	IBS Implant system
510k	K202418	K173120	K153350
Part Name	Magic UCLA Screw Retained Type	Burn out core cylinder	UCLA Abutment
Materials	Co-Cr-Mo Alloy Poly Diacetate	Co-Cr-Mo Alloy Poly Diacetate	Titanium Alloy Poly Diacetate
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Indications for Use	The Magic UCLA Abutment System is intended to replace missing teeth to restore chewing function. The Magic UCLA Abutment System can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.	The CCM Abutment System is intended to replace missing teeth to restore chewing function. The CCM Abutment System can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.	The IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.
Principle of Operation	A screw retained restoration type of abutment using a screw to fix a prosthesis.	A screw retained restoration type of abutment using a screw to fix a prosthesis.	A screw retained restoration type of abutment using a screw to fix a prosthesis.
Hex			
Dimensions	4.5, 5.2, 6.2mm (Ø) X 10.2, 10.4, 10.5mm (L)	5, 6mm (Ø) X 8.5, 8.65mm (L)	3.5, 4, 4.5, 5, 5.5mm (Ø) X 14, 15, 16, 17mm (L)
Restoration angulations	No Angle	No Angle	No Angle

Design			
Non-Hex			
Dimensions	4.5, 5.2, 6.2mm (Ø) X 10.2, 10.4, 10.5mm (L)	5, 6mm (Ø) X 8.5, 8.65mm (L)	3.5, 4, 4.5, 5, 5.5mm (Ø) X 14, 15, 16, 17mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			

Similarities

The Magic UCLA Screw Retained Type is substantially equivalent in indications for use, fundamental scientific technology, principle of operation, functions, and materials as the identified predicates.

Differences

Compared to the primary predicate device, new abutments with various dimensions are added to the subject system. To support the dimension differences between the primary predicate device and subject device, K153350 was added as the reference device. The dimensions of the subject device are in range of the dimensions of the reference device and the slight difference does not affect the application and fundamental scientific technology of the device. Therefore, it is concluded that the Magic UCLA Screw Retained Type is substantially equivalent with the predicate devices.

Magic UCLA Cement Retained Type (Hex, Non-Hex)			
Device Name	**Subject Device**	**Primary Predicate Device**	**Reference Predicate Device**
	Magic UCLA Abutment System	CCM Abutment System	IBS Implant system
510k	K202418	K173120	K153350
Part Name	Magic UCLA Cement Retained Type	Burn out core cap	UCLA Abutment
Materials	Co-Cr-Mo Alloy Poly Diacetate	Co-Cr-Mo Alloy Poly Diacetate	Titanium Alloy Poly Diacetate
Manufacturer	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.	InnoBioSurg Co., Ltd.
Indications for Use	The Magic UCLA Abutment System is intended to replace missing teeth to restore chewing function. The Magic UCLA Abutment System can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.	The CCM Abutment System is intended to replace missing teeth to restore chewing function. The CCM Abutment System can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.	The IBS Implant System is intended to replace missing teeth to restore chewing function. The IBS Implant can be placed in support of single or multiple-unit restorations including: cement retained, screw retained, or overdenture restorations, and terminal or immediate abutment support for fixed bridgework. This system is for one or two stage surgical procedures. This system is intended for delayed loading.
Principle of Operation	A screw retained restoration type of abutment using a screw to fix a prosthesis.	A screw retained restoration type of abutment using a screw to fix a prosthesis.	A screw retained restoration type of abutment using a screw to fix a prosthesis.
Hex			
Dimensions	4.5, 5.2, 6.2mm (Ø) X 10.5, 11.1mm (L)	5, 6mm (Ø) X 9.15mm (L)	3.5, 4, 4.5, 5, 5.5mm (Ø) X 14, 15, 16, 17mm (L)
Restoration angulations	No Angle	No Angle	No Angle

Design			
Non-Hex			
Dimensions	4.5, 5.2, 6.2mm (Ø) X 10.5, 11.1mm (L)	5, 6mm (Ø) X 9.15 mm (L)	3.5, 4, 4.5, 5, 5.5mm (Ø) X 14, 15, 16, 17mm (L)
Restoration angulations	No Angle	No Angle	No Angle
Design			

Similarities

The Magic UCLA Cement Retained Type is substantially equivalent in indications for use, fundamental scientific technology, principle of operation, functions, and materials as the identified predicates.

Differences

Compared to the primary predicate device, new abutments with various dimensions are added to the subject system. To support the dimension differences between the primary predicate device and subject device, K153350 was added as the reference device. The dimensions of the subject device are in range of the dimension of the reference device and the slight difference does not affect the application and fundamental scientific technology of the device. Therefore, it is concluded that the Magic UCLA Cement Retained Type is substantially equivalent with the predicate devices.

Non-Clinical Data

Non-clinical testing was not performed for the subject device because the subject device and predicate devices are substantially equivalent in indications, fundamental scientific technology, materials, and design. By performing the product's design controls activity summary, it is concluded that any differences do not impact the product's safety and effectiveness and demonstrate substantial equivalence.

The tests below were performed for the predicate devices and leveraged for the subject device:

- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-11:2006 referenced in K173120
- Galvanic Reaction Test between CoCr alloy and non-precious metals referenced in K173120
- End User Steam Sterilization Test according to ISO 17665-1:2006, -2:2009, and ANSI/AAMI ST79 referenced in K192197

The results of the above tests have met the criteria of the standards, and demonstrated substantial equivalence with the predicate devices.

The Biocompatibility Test was conducted on the primary predicate and leveraged for the subject device because both products are manufactured with the same materials and undergo the same manufacturing process. It demonstrates that the subject device is biocompatible and substantially equivalent with the predicate.

The galvanic reaction testing between the CoCr alloy and non-precious dental alloys, Ti Grade 5, was performed on the primary predicate and compatible implants. Per FDA guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", corrosion potential of each CoCr and Ti Grade 5 alloy and couple potential for assembled CoCr and Ti Grade 5 alloy were assessed.

The end user sterilization test was performed for the predicate device, K192197, and leveraged for the subject device because the product category, materials, manufacturing process, facility, and packaging is the exactly the same as the predicate, K192197.

Mechanical testing such as fatigue testing was not performed for the subject device because per FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", the Magic UCLA Abutment System is not intended to be cast at angulation or placed to provide angular correction.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate devices.

Conclusions

The Magic UCLA Abutment System, subject device of this submission, 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 the predicate devices. Therefore, the Magic UCLA Abutment System is substantially equivalent.