January 5, 2022

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

Re: K211978
Trade/Device Name: Jplant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 22, 2021
Received: October 7, 2021

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 (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 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)*
K211978

Device Name
Jplant

Indications for Use *(Describe)*
Jplant is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Jplant is for single stage and 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.

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510(k) Summary

(K211978)

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

1. **Date:** 1/4/2022

2. **Applicant / Submitter**

JJ Medical Co., Ltd.
Daeryung Techno Town 3 409 Gasan-Dong,
115, Gasan Digital 2-Ro, Geumcheon-Gu
Seoul, Republic of Korea, 08505

3. **U.S. Designated Agent**

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. **Trade/Proprietary Name:**

Jplant

5. **Common Name:**

Endosseous dental implant

6. **Classification:**

Endosseous dental implant (21CFR 872.3640, Product code DZE, Class 2, Dental)

7. **Device Description:**

The Jplant is dental implant which is made of titanium alloy intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices such as artificial teeth, and to restore the patients chewing function. The fixture has the following sizes.

Size
RP (Regular Platform) Connection Type Fixture 3.90mm Dia. x 7.0mm(L) / 8.0mm (L) / 10.0mm (L) /12.0mm (L) / 14.0mm (L) 4.21mm Dia. x 7.0mm(L) / 8.0mm (L) / 10.0mm (L) /12.0mm (L) / 14.0mm (L) 4.67mm Dia. x 7.0mm(L) / 8.0mm (L) / 10.0mm (L) /12.0mm (L) / 14.0mm (L) 5.14mm Dia. x 7.0mm(L) / 8.0mm (L) / 10.0mm (L) /12.0mm (L) / 14.0mm (L) 6.20mm Dia. x 7.0mm(L) / 8.0mm (L) / 10.0mm (L) /12.0mm (L) 7.20mm Dia. x 7.0mm(L) / 8.0mm (L) / 10.0mm (L) /12.0mm(L)

The system includes the cover screw which is the same as the K160536 with a slight difference in size. The cover screw is made of Ti6AL4V ELI, ASTM F136 and offers the size of 3.55mm Dia. x 6.35mm (L).

The Jplant dental implant is intended to be used with abutments cleared under K160536 and manufactured by Medimecca Co., Ltd. JJ Medical Co., Ltd. is a subsidiary company of Medimecca Co., Ltd. and is under the same management, and shares the same manufacturing method and processes.

8. Indication for use:

Jplant is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Jplant is for single stage and two stage surgical procedures. This system is intended for delayed loading.

9. Predicate Devices:

Primary Predicate Device

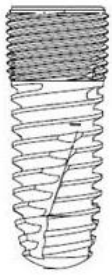
- Manufacturer: MEDIMECCA Co., Ltd.
- Device: CHAORUM Implant System
- 510(k) Number: K160536

Reference Device

- Manufacturer: Dentis Co., Ltd.
- Device: OneQ-SL s-Clean Implant System
- 510(k) Number: K153639

10. Substantial Equivalence:

The Jplant has the same intended use as the identified predicate devices. They are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium SLA roughened surfaces. The subject and predicate devices are both bone-level implants that share similar body shape design such as straight walled neck and tapered body design. We identified reference device which covers the size range of the subject device. Based on the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices.

Item	Subject Device	Primary Predicate Device	Reference Device
510(K) Number	K211978	K160536	K153639
Device Name	Jplant	CHAORUM Implant System	OneQ-SL s-Clean Implant System
Manu-facturer	JJ MEDICAL Co., Ltd.	MEDIMECCA Co., Ltd.	Dentis Co., Ltd.
Indications for Use	JFT Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. JFT Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	CHAORUM Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. CHAORUM Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	The OneQ-SL s-Clean Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.
Design /Principle of Operation	 - Internal Hexagon connection - Self-tapping cutting edge threads	 	  - Internal Hex-connected - Submerged Fixture -Bone level -

		 - Internal Hexagon connection - Self-tapping cutting edge threads	Tapered & straight body - 3 sided cutting edge with self-tapping
Endosseous Implant Material	Titanium (ASTM F67)	Titanium (ASTM F136, ASTM F67)	Titanium (ASTM F67)
Surface Treatment	SLA	RBM, SLA	SLA
Implant Sterilization Method	Radiation Sterile	Radiation Sterile	Radiation Sterile
Implant Diameters x Implant Lengths	3.90mm Dia. x 7.0mm (L) 3.90mm Dia. x 8.0mm (L) 3.90mm Dia. x 10.0mm (L) 3.90mm Dia. x 12.0mm (L) 3.90mm Dia. x 14.0mm (L)	3.25mm Dia. x 8.0mm(L) 3.25mm Dia. x 8.5mm(L) 3.25mm Dia. x 10.0mm(L) 3.25mm Dia. x 12.0mm(L) 3.25mm Dia. x 14.0mm(L) 3.25mm Dia. x 15.0mm(L) 3.25mm Dia. x 15.5mm(L)	3.7mm Dia. x 7.0mm (L) 3.7mm Dia. x 8.0mm (L) 3.7mm Dia. x 10.0mm (L) 3.7mm Dia. x 12.0mm (L) 3.7mm Dia. x 14.0mm (L)
	4.21mm Dia. x 7.0mm (L) 4.21mm Dia. x 8.0mm (L) 4.21mm Dia. x 10.0mm (L) 4.21mm Dia. x 12.0mm (L) 4.21mm Dia. x 14.0mm (L)	3.89mm Dia. x 8.0mm(L) 3.89mm Dia. x 10.0mm(L) 3.89mm Dia. x 12.0mm(L) 3.89mm Dia. x 14.0mm(L)	3.9mm Dia. x 7.0mm (L) 3.9mm Dia. x 8.0mm (L) 3.9mm Dia. x 10.0mm (L) 3.9mm Dia. x 12.0mm (L) 3.9mm Dia. x 14.0mm (L)
	4.67mm Dia. x 7.0mm (L) 4.67mm Dia. x 8.0mm (L) 4.67mm Dia. x 10.0mm (L) 4.67mm Dia. x 12.0mm (L) 4.67mm Dia. x 14.0mm (L)	3.89mm Dia. x 8.0mm(L) 3.89mm Dia. x 10.0mm(L) 3.89mm Dia. x 12.0mm(L) 3.89mm Dia. x 14.0mm(L)	4.2mm Dia. x 7.0mm (L) 4.2mm Dia. x 8.0mm (L) 4.2mm Dia. x 10.0mm (L) 4.2mm Dia. x 12.0mm (L) 4.2mm Dia. x 14.0mm (L)
	5.14mm Dia. x 7.0mm (L) 5.14mm Dia. x 8.0mm (L) 5.14mm Dia. x 10.0mm (L) 5.14mm Dia. x 12.0mm (L) 5.14mm Dia. x 14.0mm (L)	4.28mm Dia. x 8.0mm(L) 4.28mm Dia. x 10.0mm(L) 4.28mm Dia. x 12.0mm(L) 4.28mm Dia. x 14.0mm(L)	4.7mm Dia. x 7.0mm (L) 4.7mm Dia. x 8.0mm (L) 4.7mm Dia. x 10.0mm (L) 4.7mm Dia. x 12.0mm (L) 4.7mm Dia. x 14.0mm (L)
	6.20mm Dia. x 7.0mm (L) 6.20mm Dia. x 8.0mm (L) 6.20mm Dia. x 10.0mm (L) 6.20mm Dia. x 12.0mm (L)	4.78mm Dia. x 8.0mm(L) 4.78mm Dia. x 10.0mm(L) 4.78mm Dia. x 12.0mm(L) 4.78mm Dia. x 14.0mm(L)	5.2mm Dia. x 7.0mm (L) 5.2mm Dia. x 8.0mm (L) 5.2mm Dia. x 10.0mm (L) 5.2mm Dia. x 12.0mm (L) 5.2mm Dia. x 14.0mm (L)
	7.20mm Dia. x 7.0mm (L) 7.20mm Dia. x 8.0mm (L) 7.20mm Dia. x 10.0mm (L) 7.20mm Dia. x 12.0mm (L)	5.28mm Dia. x 8.0mm(L) 5.28mm Dia. x 10.0mm(L) 5.28mm Dia. x 12.0mm(L) 5.28mm Dia. x 14.0mm(L)	6.0mm Dia. x 7.0mm (L) 6.0mm Dia. x 8.0mm (L) 6.0mm Dia. x 10.0mm (L) 6.0mm Dia. x 12.0mm (L)
		6.28mm Dia. x 8.0mm(L) 6.28mm Dia. x 10.0mm(L) 6.28mm Dia. x 12.0mm(L) 6.28mm Dia. x 14.0mm(L)	7.0mm Dia. x 7.0mm (L) 7.0mm Dia. x 8.0mm (L) 7.0mm Dia. x 10.0mm (L) 7.0mm Dia. x 12.0mm (L)

			8.0mm Dia. x 7.0mm (L) 8.0mm Dia. x 8.0mm (L) 8.0mm Dia. x 10.0mm (L) 8.0mm Dia. x 12.0mm (L)

11. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137.
- Five year of shelf life has been validated through accelerating testing in accordance with ASTM F1980-07, ASTM F88, ISO 11607, and ISO 11737-2.
- XPS(X-ray Photoelectron Spectroscopy) and SEM(Scanning Electron Microscope) were performed to evaluate the fixture surface characteristics after SLA treatment.
- Biocompatibility information for the subject device is leveraged from the K160536 clearance. The following tests were performed under the submission.

No	Test Title	Test Standard
1	Cytotoxicity Test	ISO10993-5:2009
2	Acute Systemic Toxicity Test	ISO10993-11:2006
3	Intracutaneous Reactivity Test	ISO10993-10:2010
4	Pyrogen Test	ISO10993-11:2006
5	Local Lymph Node Assay, LLNA Test	ISO10993-10:2010
6	Bone Implantation Test	ISO10993-6:2007

- The endotoxin testing will be conducted on a random batch every two months for the subject device. 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).

12. Conclusion

The subject devices and the predicate device have the same intended use and have similar technological characteristics. The substantial equivalence of the different dimensions between the subject device and predicate device is supported by the reference device.

Overall, the Jplant has the following similarities to the predicate device:
* have the same intended use,
* use the same operating principle,
* incorporate similar design,
* incorporate the same material and the sterilization method

Based on the similarities, we conclude that the Jplant is substantially equivalent to the predicate devices.