DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

KJ Meditech Co., Ltd.
Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417
Irvine, California 92620

November 9, 2017

Re: K161923
Trade/Device Name: J2A SLA Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 7, 2017
Received: October 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K161923

Device Name
J2A SLA Dental Implant System

Indications for Use *(Describe)*
The J2A SLA Dental 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. The J2A SLA Dental Implant System is for single and two stage surgical procedures. These systems are 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

(K161923)

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

Date: 11/09/2017

1. Submitter

	Submitter
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2. U.S Agent/Contact Person

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3. Device

- Trade Name: J2A SLA Dental Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant System
- Product Code: DZE, NHA
- Classification regulation: 21CFR872.3640

4. Predicate Device:

J2A Dental Implant System, J2C Dental Implant System (K150060) by KJ Meditech Co., Ltd.

5. Description:

The J2A SLA Dental Implant System is internal hexagon type dental implant systems made

of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implants may be used to replace one or more missing teeth. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of the system has been treated with SLA (sandblasted, Large- grit, Acid-etched). The size information is as below.

- 3.75mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
- 4.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
- 4.30mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
- 4.50mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
- 5.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
- 5.50mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
- 6.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)

6. Indication for use:

The J2A SLA Dental 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. The J2A SLA Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.

7. Basis for Substantial Equivalence

The J2A SLA Dental Implant System has the same intended use and technical characteristics as the unmodified device. They are exactly identical except the surface treatment.

Item	Subject Device	Predicate Device
510(K) Number	-	K150060
Device Name	J2A SLA Dental Implant	J2A Dental Implant System, J2C Dental Implant System
Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.
Indications for Use	The J2A SLA Dental 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. The J2A SLA Dental Implant is for single and two stage surgical procedures. The system is intended for delayed loading.	The J2A Dental Implant System, J2C Dental Implant System are 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. The J2A Dental Implant System, J2C Dental Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.
Design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design

Appearance		
Endosseous Implant Material	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136
Surface Treatment	SLA Treatment	RBM Treatment
Sterilization Method	Gamma	Gamma
Implant Diameters	3.75mm, 4.0mm, 4.3mm, 4.5mm, 5.0 mm, 5.5mm, 6.0mm	3.75mm, 4.0mm, 4.3mm, 4.5mm, 5.0 mm, 5.5mm, 6.0mm
Implant Lengths	7mm – 15.0 mm	7mm – 15.0 mm

8. Non-Clinical Testing

Risk analysis was conducted according to ISO14971 to evaluate the effect of the modification which is surface treatment change from RBM to SLA for fixtures. Through risk analysis and the following validation/verification tests, we conclude that the J2ASLA Dental Implant System is substantially equivalent to the unmodified device.
The following tests were carried out:
- SEM surface analysis
- EDS Surface chemistry analysis
- Cytotoxicity test (10993-5)
- Skin sensitization test (10993-10)
- Intracutaneous reactivity test (10993-10)
- Sterilization validation test (ISO 11137-1 & ISO 11137-2)
- Shelf life validation test: visual inspection, label, seal inspections (ASTM F88), dye penetration (ISO 11607-1 & 11607-2) and microbial challenge (ISO11737-2).

Fatigue testing was not conducted because the subject device does not have an angled abutment.

The USP <85> test method will be used to evaluate pyrogen limit specifications for the subject device. The endotoxin testing will be conducted on every batch for the subject device and the testing limit will be below 0.5 EU/mL. We referenced the USP 39 <85> to device on the endotoxin limit which is 0.5 EU/mL.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the J2A SLA Dental Implant system has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the same design,
* incorporate the same material and the sterilization method.

Based on the similarities, we conclude that the J2A SLA Dental Implant system is substantially equivalent to the predicate device.