March 1, 2022

KJ Meditech Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K202046
Trade/Device Name: LOTA SLA Dental Implant System and LOTA HA Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 9, 2022
Received: February 18, 2022

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)*

Device Name
LOTA SLA Dental Implant System and LOTA HA Dental Implant System

Indications for Use *(Describe)*
The LOTA SLA Dental Implant System and LOTA HA 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 LOTA SLA Dental Implant System and LOTA HA Dental Implant System are 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.

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510(k) Summary

(K202046)

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

Date: 2/28/2022

1. Submitter

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Tel: +82-62-972 -5476

Contract Person: Hyuckki Moon / President

2. U.S Agent/Contact Person

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3. Device

- Trade Name: LOTA SLA Dental Implant System
  LOTA HA Dental Implant System
- Common Name: Dental implant system
- Classification Name: Endosseous dental implant
- Product Code: DZE, NHA
- Classification regulation: 21 CFR 872.3640

4. Predicate Device

- Primary Predicate:
  - KJ Submerged System by KJ Meditech Co., Ltd. (K103810)
- Reference Devices:

- Bicon Implants with a 2.5mm Internal Connection by BICON, LLC (K092035)
- Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge® Implant System by Megagen Implant Co., Ltd. (K170044)
- J2a Dental Implant System, J2c Dental Implant System by KJ Meditech Co., Ltd. (K150060)
- J2A SLA Dental Implant System by KJ Meditech Co., Ltd. (K161923)

5. Device Description

The LOTA SLA Dental Implant system and LOTA HA Dental Implant System are dental implant systems made of Titanium 6AL 4V ELI alloy, which confirms to ASTM F136, 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. All diameters are available with all lengths.

Implant Diameter	3.8mm, 4.3mm, 4.8mm, 5.3mm, 6.3mm, 7.3mm
Implant Length	8.0mm, 9.0mm, 10.0mm,11.0mm, 12.0mm,13.0mm, 14.0mm

The implants are used with the following abutments. The Shouldered Abutments and the Shouldered Hex Abutments have internal connection structure, and they adopt locking taper connection. They restore fixed crown and bridge restorations. The Shouldered Removal Abutment uses screw and locking taper connection to be connected with the fixture. It has the same intended use as the other abutments. All the abutments are not intended for angulation.

- Shouldered Abutment
- Shouldered Hex Abutment
- Shouldered Removal Abutment

The systems are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

6. Indication for Use

The LOTA SLA Dental Implant System and LOTA HA 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 LOTA SLA Dental Implant System and LOTA HA Dental Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.

7. Basis for Substantial Equivalence

The subject device and the predicate device (KJ Submerged System, K103810) have the same indications and fundamental scientific technology. The subject and predicate devices employ the same materials and have very similar in design. The fixture thread design, the fixture size, and abutment design have changed, and we have identified a reference device which are similar in design and size. The Bicon Implants (K092035) has similar thread design, and the J2a Dental Implant System, J2c Dental Implant System have similar neck micro-threading design. We identified MegaGen AnyRidge® Implant System (K170044) as a reference device which encompasses the size range of the subject device.

Another difference is that the subject fixtures have SLA treatment. This difference poses potential risks in biocompatibility, sterilization/shelf-life validation, and residual remining on the fixtures. To mitigate these risks, we identified a predicate device made by our company(K161923) which go through the same manufacturing processes and have the same material/surface treatment. Also, we performed sterilization/shelf-life validation tests, and SEM analysis to validate that the modification would not raise an issue to support substantial equivalence.

LOTA SLA/HA Fixture

Item	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
510(K) Number	K202046	K103810	K092035	K170044	K150060	K161923
Device Name	LOTA SLA/ HA Dental Implant	KJ Submerged System	Bicon Implants with a 2.5mm Internal Connection	Inclusive® Titanium Abutments compatible with: MegaGen AnyRidge® Implant System	J2a Dental Implant System, J2c Dental Implant System	J2A SLA Dental Implant
Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.	BICON, LLC	Megagen Implant Co.,Ltd.	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.
Indications for Use	The LOTA SLADental 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,	The KJ Submerged System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented	The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial	Inclusive® Titanium Abutments are premanufactured prosthetic components connected to endosseous dental implants in the edentulous or partially edentulous maxilla or mandible to provide support for cement-retained or	The J2C 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,	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

	screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The LOTA SLA Dental Implant is for single and two stage surgical procedures. The system is intended for delayed loading.	retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The KJ Submerged System is for single and two stage surgical procedures. The system is intended for delayed loading.	dentures, or as a single tooth replacement.	screw-retained prosthetic restorations.	screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The J2C Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.	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.
Design	• Implant Type: Bone Level Implant • Connection Type: Internal Locking Taper • Neck Design: Straight walled neck • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection : Internal Locking Taper • Neck Design: Straight walled neck • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection: Internal Locking Taper • Neck Design: Straight walled neck • Body Design: Tapered design	All digitally designed abutments for use with Inclusive Abutments for CAD/CAM are intended to be sent to a Prismatik Dental craft validated milling center for manufacture. Compatible Implant System: MegaGen AnyRidge® Implant System Inclusive Titanium Abutments compatible with MegaGen AnyRidge Implant System	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck • Body Design: Tapered design
Endosseous Implant Material	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136
Surface Treatment	SLA Treatment	RBM Treatment HA Coating	HA Coating	S-L-A with Nano Ca2+ incorporated	RBM Treatment	SLA Treatment

Sterilization Method	Gamma	Gamma	Gamma	Gamma	Gamma	Gamma
Implant Diameters	3.8mm, 4.3mm, 4.8mm, 5.3mm, 6.3mm, 7.3mm	3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0 mm	4.0 mm, 4.5mm	3.5mm, 4.0mm, 4.4mm, 4.9mm 5.4mm, 5.9mm 6.4mm, 6.9mm 7.4mm, 7.9mm 8.4mm	3.75mm, 4.00mm, 4.30mm, 4.50mm, 5.00mm, 5.50mm, 6.00mm	3.75mm, 4.0mm, 4.3mm, 4.5mm, 5.0 mm, 5.5mm, 6.0mm
Implant Lengths	8.0mm, 9.0mm, 10.0mm, 11.0mm, 12.0mm, 13.0mm, 14.0mm	8.10mm, 8.30mm, 8.64mm, 8.91mm 9.00mm, 9.69mm, 10.0mm, 11.0mm, 12.0mm, 14.0mm	5.0mm, 6.0 mm, 8.0 mm, 11.0mm	7.0mm, 8.5mm 10.0mm, 11.5mm 13.0mm, 15.0mm	7mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm, 15mm	7mm – 15.0 mm
Cover Screw	N/A	N/A	N/A	N/A	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136

LOTA Abutment

LOTA Shouldered Abutments

Item	Subject Device	Predicate Device
510(K) Number	K202046	K103810
Device Name	LOTA SLA Dental Implant	KJ Submerged System
Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.
One Piece Abutment	▪ Ti 6Al 4V ELI, ASTM F136 ▪ Well : Ø2.0~ Ø3.0 ▪ Diameter: Ø4.0mm ~ Ø6.5mm ▪ Height:6.85mm~11.35mm Post Length: 2mm~4mm	▪ Ti6Al4V ELI, ASTM F136 ▪ Well: Ø 2.0~ Ø 3.0 ▪ Diameter: Ø3.5mm~ Ø6.0mm ▪ Height:10.7mm~15mm ▪ Post Length: 4mm~6mm

LOTA Shouldered Removal Abutments

Item	Subject Device	Predicate Device
510(K) Number	K202046	K161923
Device Name	LOTA SLA Dental Implant	J2A SLA Dental Implant System
Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.

Two Piece Abutment	▪ Ti 6Al 4V ELI, ASTM F136 ▪ Well : Ø2.5~ Ø3.0 ▪ Diameter: Ø5.0mm ~ Ø6.5mm ▪ Height:6.85mm~11.35mm ▪ Post Length: 2mm~4mm	▪ Ti 6Al 4V ELI, ASTM F136 ▪ TiN Coating ▪ Well : Ø2.78~ Ø3.33 ▪ Diameter: Ø4~ Ø7 ▪ Cuff:1mm~5mm Height:4.0mm~7.0mm

8. Non-Clinical Testing

Risk analysis was conducted according to ISO14971 to evaluate the effect of the modification and based on the analysis, the following activities/tests were performed.

- Identifying reference devices for the modifications in fixture thread design, the fixture size, and abutment design to make sure the subject device is not introducing new design or size range which will raise a concern.
- For the modification in surface treatment, identifying a predicate device which is made by our company having the same material/surface treatment and going through the same manufacturing processes.
- Sterilization validation test in accordance with ISO 11137-1 and 11137-2, and shelf life validation tests in accordance with ASTM F1980-7, ASTM F88, ISO 11607, and ISO 11737-2.
- Endotoxin testing for lot release was evaluated in accordance with USP 39 <85> the endotoxin limit which is 0.5 EU/mL.
- Scanning Electron Microscopy (SEM) to validate there is no residual remaining on the implants.

9. Conclusion

Based on the similarities and the test results of the validation activities, we conclude that the LOTA SLA Dental Implant System and LOTA HA Dental Implant System are substantially equivalent to the predicate device.