DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 21, 2016

KJ Meditech Co., Ltd.
c/o Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110
Fullerton, California 92831

Re: K151970
Trade/Device Name: KJ Mini Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 22, 2016
Received: September 22, 2016

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 yours,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151970

Device Name

KJ Mini Implant System

Indications for Use *(Describe)*

The KJ Mini Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 2.0mm, 2.5mm, and 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The KJ Mini Implant System is intended for single use only. It is 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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K151970

510(k) Summary

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

Date: 10/20/2016

1. Applicant / Submitter

	Submitter
Name	KJ Meditech Co., Ltd.
Address	959-21 Daechon-dong, Buk-gu,Gwang-ju, 500-470, South Korea
Phone	+82-62-972-5476
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Contact	Huykki Moon, CEO

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110, Fullerton, CA 92831
Phone: 714.202.5789 Fax: 714-409-3357
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3. Device

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

4. Predicate Device:

- **Primary Predicate Device:**
  One Plus Implant System by OsseoFuse Co., Ltd. (K133050)
- **Reference Predicate Device:**
  MS System by OSSTEM Implant Co., Ltd. (K083067)

Spectra System by Implant Direct LLC (K061319)
Intra-Lock Dental Implant System with Blossom by Intra-Lock International Inc. (K103194)
MILO Dental Implant System by Intra-Lock International Inc. (K050970)
MS System(Denture) by OSSTEM Implant Co., Ltd. (K072959)

5. Device Description:

KJ Mini Implant System is a dental implant system made of Titanium 6AL 4V ELI Gr.23 alloy intended to be surgically placed in the bone of the upper or lower jaw arches. 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 fixture part has been treated with R.B.M. The KJ Mini Implant System offers the following implants with various sizes.

	OneBody Implant	Post Implant	Ball Implant
Implant Diameters	2.50mm, 2.80mm, 3.00mm, 3.30mm, 3.50mm, 3.80mm, 4.00mm, 4.30mm, 4.50mm, 4.80mm, 5.00mm, 5.30mm	3.50mm, 4.00mm, 4.50mm, 5.00mm	2.00mm, 2.50mm, 3.00mm, 3.50mm, 4.00mm, 4.50mm, 5.00mm
Implant Lengths	• (for 2.50mm-3.00mm Dia.) 10mm, 11mm, 12mm, 13mm, 14mm, 15mm • (for 3.30mm to 5.30mm Dia.) 10mm, 11mm, 12mm, 13mm, 14mm,15mm, 16mm	10mm, 11mm, 12mm, 13mm, 14mm,15mm, 16 mm	• (for 2mm to 3mm): 10mm, 11mm,12mm,13mm, 14mm,15mm • (for 3.5mm to 5mm): 10mm, 11mm, 12mm, 13mm,14mm,15mm, 16mm

Post Abutment is offered for Post Implant and it offers straight type only. Ball Attachment is offered for Ball Implant. Both Post Abutment and Ball Attachments are made of Ti 6Al 4V ELI, Gr.23.

All the implant types of the KJ Mini Implant System are straight only.

6. Indication for use:

The KJ Mini Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 2.0mm, 2.5mm, and 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The KJ Mini Implant System is intended for single use only. It is for delayed loading.

7. Basis for Substantial Equivalence

The KJ Mini Implant System 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.

The subject and predicate devices are similar in design, size, materials, and are sterilized via gamma irradiation for fixtures.

7.1. OneBody Implant

	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device3
510(K) Number	K151970	K133050	K083067	K061319
Device Name	KJ Mini Implant System	One Plus Implant System	MS System	Spectra System (One Piece Implants)
Applicant	KJ Meditech Co., Ltd.	OsseoFuse Co., Ltd.	OSSTEM Implant Co., Ltd.	Implant Direct LLC
Contract Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.	-	-
Indications for Use	The KJ Mini Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 2.0mm, 2.5mm, and 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The KJ Mini Implant System is intended for single use only. It is for delayed loading.	The One Plus Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The One Plus Implant System is intended for single use only. It is for delayed loading.	The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) is intended for single use only. It is not for immediate loading.	The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage or two stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established. The ScrewDirect 3.0rmm implant is indicated for: 1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors

				and maxillary lateral incisors.
Technological characteristics	• Implant Type: One Piece Type • RBM Treatment on the fixture body • Body Design: Threaded body	• Implant Type: One Piece Type • RBM Treatment on the fixture body • Body Design: Threaded body	• Implant Type: One Piece Type • RBM Treatment on the fixture body • Body Design: Threaded body	• Threaded, root form implant • Tapered threaded body with an integrated abutment • Self-tapping
Principles of Operation	One piece type which a fixture and an abutment are integrated.	One piece type which a fixtu re and an abutment are integ rated.	One piece type which a fixtu re and an abutment are integ rated.	One piece type which a fixture and an abutment are integrated.
Appearance				
Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Titanium Alloy
Surface Treatment	RBM Treatment on the fixture body	RBM Treatment on the fixture body TiN coating on the abutment	RBM Treatment on the fixture body	RBM Treatment on the fixture body
Implant Sterile	Yes	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma	Gamma
Restoration type	Single unit, Multi unit	Single Unit, Multi unit	Single Unit, Multi unit	Single Unit, Multi unit
Implant Diameters	2.50mm, 2.80mm, 3.00mm, 3.30mm, 3.50mm, 3.80mm, 4.00mm, 4.30mm, 4.50mm, 4.80mm, 5.00mm, 5.30mm	3.00mm, 3.75mm, 4.50mm, 5.25mm	2.50mm 3.00mm	3.0mm, 3.7mm, 4.7mm, 5.7 mm
Implant Lengths	• (for 2.50mm-3.00mm Dia.) 10mm-15mm	11.5mm, 13mm, 14.5mm	10.0 mm, 13.0mm, 15.0mm	10mm, 13mm, 16mm

	• (for 3.30mm to 5.30mm Dia.) 10mm-16mm			
Product Code	DZE	DZE	DZE	DZE

Substantial Equivalence Discussion

The subject device is substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented. Based on the comparison analysis, similar intended use, comparable technological characteristics, and similar general design features, the subject device is substantially equivalent to the predicate devices. There are no significant differences between the KJ Mini Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to the predicate devices in design, function, material and intended use.

7.2. Post Implant

	Subject Device	Predicate Device1	Predicate Device2
510(K) Number	K151970	K103194	K050970
Device Name	KJ Mini Implant System	Intra-Lock Dental Implant System with Blossom	MILO Dental Implant System
Manufacturer	KJMEDITECH Co., Ltd.	Intra-Lock International Inc.	Intra-Lock International Inc.
Indications for Use	The KJ Mini Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 2.0mm, 2.5mm, and 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The KJ Mini Implant System is intended for single use only. It is for delayed loading.	The Intra-lock Dental Implant system has been designed to restore partially or fully edentulous patients. The Implant have been designed to be used in either the mandible or the maxilla and to support removable or fixed prosthesis from Single tooth replacement to full arch reconstruction. They are intended for immediate function on single and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore	MILO Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants may be restored after a period of time or placed in immediate function.

		normal teeth functions	
Technological characteristics	• Implant Type: Mini Implant Type • Neck Design: Straight walled neck • RBM Treatment on the fixture body • Body Design: Threaded body	• Implant Type: Mini Implant Type • Neck Design: Straight walled neck • Body Design: Threaded body	• Implant Type: Mini Implant Type • Neck Design: Straight walled neck • Body Design: Threaded body
Principles of Operation	Fix the abutment to the implant by friction	Fix the abutment to the implant by friction	Fix the abutment to the implant by friction
Appearance			
Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	RBM Treatment on the fixture body	RBM Treatment on the fixture body	RBM Treatment on the fixture body
Implant Sterile	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma
Restoration type	Single unit, Multi unit	Single Unit, Multi unit	Single Unit, Multi unit
Implant Diameters	3.50mm, 4.00mm, 4.50mm, 5.00mm	3.4mm.4.0mm 6.0mm	3.0mm
Implant Lengths	10 – 16 mm	10mm~18mm	10mm~15mm

Abutment Appearance			
Abutment Total Length	9.0mm~9.5mm	7.3mm ~ 10mm	7.3mm ~ 10mm
Abutment Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Abutment Surface Treatment	None	None	None
Abutment Type	Straight	Straight, Angled	Straight, Angled

Substantial Equivalence Discussion

The subject device is substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented. Based on the comparison analysis, similar intended use, comparable technological characteristics, and similar general design features, the subject device is substantially equivalent to the predicate devices. There are no significant differences between the KJ Mini Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to the predicate devices in design, function, material and intended use.

7.3. Ball Implant

	Subject Device	Predicate Device	Predicate Device	Predicate Device
510(K) Number	K151970	K072959	K103194	K050970
Device Name	KJ Mini Implant System	MS System(Denture)	Intra-Lock Dental Implant System with Blossom	MILO Dental Implant System
Manufacturer	KJ Meditech Co., Ltd.	OSSTEM Implant Co., Ltd.	Intra-Lock International Inc.	Intra-Lock International Inc.
Indications for Use	The KJ Mini Implant System is intended to use in the treatment of missing teeth to support prosthetic device, such as artificial teeth, in order to restore mastication in partially edentulous patients. 2.0mm, 2.5mm, and 3.0mm diameter implants are intended to be used in central or lateral mandibular incisors. The KJ Mini Implant System is intended for single use only. It is for delayed loading.	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only.	The Intra-lock Dental Implant system has been designed to restore partially or fully edentulous patients. The Implant have been designed to be used in either the mandible or the maxilla and to support removable or fixed prosthesis from Single tooth replacement to full arch reconstruction. They are intended for immediate function on single and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions	MILO Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants may be restored after a period of time or placed in immediate function.
Design	• Implant Type: Ball Shape Head Implant Type • RBM Treatment on the fixture body • Body Design: Threaded body	• Implant Type: Ball Shape Head Implant Type • RBM Treatment on the fixture body • Body Design: Threaded body	• Implant Type: Mini Implant Type • Neck Design: Straight walled neck • Body Design: Threaded body	• Implant Type: Mini Implant Type • Neck Design: Straight walled neck • Body Design: Threaded body
Principles of Operation	Ball shaped implant head allowing for the retaining structures to snap over the ball	Ball shaped implant head allowing for the retaining structures to snap over the ball	Ball shaped implant head allowing for the retaining structures to snap over the ball	Ball shaped implant head allowing for the retaining structures to snap over the ball

Appearance				
Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	RBM Treatment on the fixture body	RBM Treatment on the fixture body	RBM Treatment on the fixture body	RBM Treatment on the fixture body
Implant Sterile	Yes	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma	Gamma
Restoration type	Overdenture	Overdenture	Overdenture	Overdenture
Implant Diameters	2.00mm, 2.50mm, 3.00mm, 3.50mm, 4.00mm, 4.50mm, 5.00mm	2.00mm 3.00mm	3.4mm.4.0mm 6.0mm	3.0mm
Implant Lengths	• (for 2mm to 3mm): 10-15mm • (for 3.5mm to 5mm): 10-16mm	10.0 mm, 13.0mm, 15.0mm	10mm~18mm	10mm~15mm
Attachment				

Substantial Equivalence Discussion

The subject device is substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented. Based on the comparison analysis, similar intended use, comparable technological characteristics, and similar general design features, the subject device is substantially equivalent to the predicate devices. There are no significant differences between the KJ Mini Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to the predicate devices in design, function, material and intended use.

8. Non-Clinical Testing

- Sterilization validating testing
  - according to ISO 11137-1 & ISO 11137-2 for implants
  - according to ISO 17665-1 & ISO 17665-2 for abutments
- Three year shelf life testing according to ASTM F1980
- Chemical and SEM Analysis

9. Conclusion

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

Overall, the KJ Mini Implant System has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the same basic design,
* incorporate the same material and the surface treatment

Based on the similarities, we conclude that the KJ Mini Implant System is substantially equivalent to the predicate devices.