June 28, 2018

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

Re: K173116
Trade/Device Name: KJ ZIRCONIA Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: May 24, 2018
Received: May 30, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K173116

Device Name
KJ ZIRCONIA Implant System

Indications for Use *(Describe)*

The KJ ZIRCONIA 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. 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
(K173116)

Date: 06/28/2018

1. Submitter

KJ Meditech Co., Ltd.
21, Cheomdan Venture-ro
40 Beon-gil, Buk-gu
Gwangju, Jeonranamdo, Republic of Korea 500-470

2. U.S Agent/Contact Person

Priscilla Chung / Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt, Irvine CA 92620
Phone: 714.202.5789Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

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

4. Predicate Device

- **Predicate Device:**
  Nobel Biocare (K061971) by Novel Biocare Co., Ltd.
- **Reference Device:**
  PURE Ceramic Implant (K151328) by Staumann USA

5. Description

KJ ZIRCONIA Implant System is a dental implant system made of ZIRCONIA intended to be surgically placed in the bone of the upper or lower jaw arches. It is one piece type implant which the implant and the abutment are manufactured as one piece. It offers two types: BL type and BS type, and the difference is only in the length of the abutment part.

6. Indication for Use

The KJ ZIRCONIA 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. It is for delayed loading.

7. Basis for Substantial Equivalence

The indications for use statement of the subject device does not use exactly the same words as the predicate and the reference devices; however, the statements have the same indications for use which is treatment of missing teeth.
The subject device is substantially equivalent to the predicate and the reference devices in terms of design and material. The size range of the predicate device covers that of the subject device.

	Subject Device	Predicate Device	Reference Device
Device Name	KJ ZIRCONIA Implant System	Nobel biocare	PURE Ceramic implant
510k #	K173116	K061971	K151328
Applicant	KJ Meditech Co., Ltd.	Novel biocare Co., Ltd.	Staumann USA
Indications for Use	The KJ ZIRCONIA 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. It is for delayed loading.	Nobel Biocare's Zirconia Implants are root-form endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Zirconia Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare Zirconia Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manual are satisfied.	The Straumann® PURE Ceramic Implant (Monotype) is indicated for restoration in single tooth gaps and in an edentulous or partially edentulous jaw. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The ø3.3 mm reduced diameter implants are recommended for central and lateral incisors only. The Straumann® PURE Ceramic Implant Protective Cap is intended to protect the Straumann® PURE Ceramic Implant (Monotype) during the healing phase after implant placement for up to 6 months. Temporary copings are intended to serve as a base for temporary crown or bridge restoration for the Straumann®

			PURE Ceramic Implant (Monotype) for up to 30 days.
Implant Design	• Implant Type: One Piece Type • Body Design: Threaded body	• Implant Type: One Piece Type • Body Design: Threaded body	• Implant Type: One Piece Type • Body Design: Threaded body
Implant/Abutment Connection	None (Monotype)	None (Monotype)	None (Monotype)
Allowable Angulation	Angulation not allowed	Angulation not allowed	Angulation not allowed
Appearance			
Material	Zirconia (ISO 13356)	Zirconia	Zirconia
Surface Treatment	N/A	N/A	N/A
Implant Sterile	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma
Implant Diameters	3.5, 4.0, 4.5, 5.0	3.5, 4.3 , 5.0	3.3, 4.1
Implant Lengths	8, 9, 10, 11, 12, 13, 14, 15, 16mm	10, 13, 16mm	8,10,12,14mm
Implant Neck Dimensions	2.6, 2.8, 3.0	3.5, 4.3, 5.0	3.5 , 4..8
Thread Pitch	1.0mm	-	-
Product Code	DZE	DZE	DZE

8. Non-Clinical Testing

- Sterilization validating testing in accordance with ISO11137 VDmax25, EN552, and ISO 11137
- Real time shelf tests to validate the sterility of the device through the proposed shelf life have been conducted for three (3) years. The testing includes visual, label, seal inspections (ASTM F88), dye penetration (ISO 11607-1) and microbial challenge (ISO11737-2).
- Biocompatibility tests in accordance with ISO 10993-3 and ISO 10993-6
- Endotoxin Testing in accordance with USP 39 <85> on the endotoxin limit which is 0.5 EU/mL

The tests above support that the differences which the subject device might have when comparing to the predicate devices such as in sterilization parameters, packaging configuration, and manufacturing processes do not raise a question in substantial equivalence.

9. Conclusion

Based on the information provided, the subject device is substantially equivalent to the predicate devices.