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

April 20, 2017

Osstem Implant Co. Ltd.
c/o Mr. David Kim
Hiossen Inc.
QA/RA Manager
85 Ben Fairless Dr.
Fairless Hills, PA 19030

Re: K152830
Trade/Device Name: K3
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: Class I
Product Code: EIA
Dated: March 7, 2017
Received: March 21, 2017

Dear Mr. David Kim:

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

SECTION_002

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)*
K152830

Device Name

K3

Indications for Use *(Describe)*

K3 is intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair. The dental treatment unit is intended for use in the dental clinic environment and is used by trained dentists and/or dental assistants.

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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OSSTEM Implant Co., Ltd.
1st floor, B-dong, 135 Gasan digital 2-ro,Geumcheon-gu,
Seoul, Republic of Korea. 153-759

510(k) Summary

Date: April 20, 2017

1. Company and Correspondent making the submission:

- Submitter's Name: Osstem Implant Co., Ltd.
- Address 1st floor, B-dong, 135 Gasan digital 2-ro, Geumcheon-gu, Seoul, Republic of Korea. 153-759
- Contact : Mr. Kim, Byunghoon
- Phone: +82-70-4394-5157

- Correspondent's Name: HIOSSEN Inc.
- Address: 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact: DAVID KIM
- Phone: 267 759 7031

2. Device:

Trade or (Proprietary) Name :	K3
Common or usual name :	Dental Unit and Chair
Classification Name :	Dental operative unit and accessories
Regulation Number :	21CFR872.6640
Device Classification:	Class I
Subsequent Product Code:	EIA

3. Predicate Device:

Sirona C8 (K983242)

4. Description

K3, Dental Unit and Chair, is designed for dental treatment of children and adults. It is a dental treatment unit in accordance with ISO 7494-1, ISO 7494-2 and ISO 6875. The 3-way syringe is a dental instrument in accordance with EN 1639. It aids the dental application in the mouth of the patient by supplying air, water or spray. This product is designed for use in dentistry only and may only be used by trained medical personnel K3 is similar to other commercially available products based on the intended use, the technology used, the claims, the electrical power and performance characteristics. It is substantially equivalent in design, function and intended use to the predicate devices.

(1) Design Feature

K3 dental operative unit has features of ergonomic, optimal position for treatment. Adjusted touch panel, 3way syringe and assistant touch panel, easy opening and closing arm rest.

(2) Main component of K3

K3 Mount and K3 Cart consist of the chair, unit, table, seat, stool, 3-way syringe, monitor arm, foot control and console.

(3) Technological Characteristics

K3 is AC powered dental operative units with accessories that are intended to supply power to, and serve as a base for dental device and accessories. Including a treatment chair, the dentist's element, the assistant's element and a dental light, offer several additional options and electronically control chair movements with software and water unit functions.

5. Substantial Equivalence Discussion

The K3 is substantial equivalent to the predicate device (K983242). The following comparison table is presented to demonstrate substantial equivalence.

Comparison Table

	Predicate Device	Subject Device
Product Name	Sirona C8	K3
510(k)	K983242	N/A
Manufacturer	Sirona Dental Systems GmbH	OSSTEM IMPLANT Co., Ltd.
Intended use	The Sirona C8 is an electronically controlled dental operative unit with accessories that are intended to supply power to, and serve as a base for dental devices and accessories.	K3 is intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair. The dental treatment unit is intended for use in the dental clinic environment and is used by trained dentists and/or dental assistants.
Code	EIA	EIA
Power and Utility supply	110V/220V AC electrical supply, compressed air and water	AC 100-120/220-240V, 50/60Hz, compressed air and water
Protection Class	Class 1 equipment	Class 1 equipment
Applied parts	Type B	Type B
Components	Doctors element, assistants element, flex arm, utility center with optional cuspidor, patient chair, treatment light,	Chair, Unit, Table, Seat, Stool, Chair, Unit, Table, Seat, Stool, Monitor Arm*, Hanaro Console*

	floor box.	(*K3 Cart model applied)
Installation	Available with chair mounted and cart mounted dentist element Installed by trained technicians.	Same as
Syringe	3-way syringe / Sprayvit	3-way syringe
Curing light	Mini LED	N/A
Control of Air and water	Uses pneumatically controlled vales to Water control the flow of air and water. On/off and intensity controlled by foot pedal.	Same as
Air Pressure	550 kPa/750 kPa (min/max)	500kPa(min)/750kPa(max)
Water Pressure	250 kPa/600 kPa(min/max)	250kPa(min)/600 kPa(max)
Water System	User may select self-Contained water system or city water supply	City water supply
Suction devices	HVE (High volumeevacuator) Saliva Ejectors	HVE (High volume evacuator) Saliva Ejectors
Patient load	Max. 135kg	Same as
Chair Height	Max.755mm Min. 395mm	Max. 790±10mm Min. 450±10mm
Back Rest	0° to 60°	0° to 66°
Head Rest	-10° to 45°	-10° to 45°
LiftMotor	Motor SL (electricmotor)	Hydraulic electromotor
Electrical Safety	Comply with IEC 60601-1	Same as
EMC	Comply with IEC 60601-1-2	Same as
Place of Use	Dental office, hospital	Same as
Intended Users	Dentists, Dental Hygienists, Dental Equivalent Assistants	Same as

As shown in the comparison chart for K3 of OSSTEM IMPLANT Co., Ltd., predicate device, they are substantially equivalent in terms of indication for use, technology and performance specifications. The external design of the subject device might be slightly different from the subject devices, however, the performance testing results provided in this submission supports that the subject device performs as well as the predicate devices for its intended use.

6. Indication for use

K3 is intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair. The dental treatment unit is intended for use in the dental clinic environment and is used by trained dentists and/or dental assistants.

7. Summary of Non-Clinical Performance Testing

The K3 has been subjected to extensive safety, performance, and product validations prior to release. Tests including EMC have been performed to ensure the devices comply with the US regulations.

Biocompatibility Testing

The biocompatibility evaluation for K3 components was conducted in accordance with the FDA Guidance Document and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The upholstery, waterlines, and airlines were tested for cytotoxicity (ISO 10993-5).

The components of the K3 are considered external communicating device for a duration of less than 24 hours.

Cleaning and Sterilization Validation

A representative sample of the3-Way syringe components were tested to validate that the components can withstand the steam sterilization process and that acceptable sterility is achieved using the recommended sterilization protocols. The sterilization validation testing was conducted according to ISO 17665-1:2006 and ISO 17665-2 and it validated that the reusable K3 components can be sterilized to reach an acceptable sterility assurance level.

In addition, cleaning/disinfection validation was conducted on the waterlines of the subject device. Validation was conducted using the following standards:

- ISO 16954:2015 Dentistry – Test methods for dental unit waterline biofilm treatment
- ISO 19458:2006 Water quality-Sampling for microbiological analysis
- ISO/TS 11080:2009 Dentistry – Essential characteristics of test methods for the evaluation of treatment methods intended to improve or maintain the microbiological quality of dental unit procedural water

The microbiological simulation test and physical & chemical test are performed to ensure that the Dental chair waterline is effectively cleaned.

Electrical Safety and Electromagnetic Compatibility (EMC)

Comprehensive performance testing has been conducted on the K3 in accordance FDA recognized standards. EMC testing was conducted in accordance with Standard EN/IEC 60601-1-2. Electrical, mechanical, and environmental safety testing according to Standard EN/IEC 60601-1was performed. Usability testing was conducted in accordance with Standard EN/IEC 60601-1-6 and EN/IEC 62366.

Software and System Verification and Validation

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

No.	Test Item	Standard
1	Cytotoxicity	ISO 10993-5
2	EMC Test	EN 60601-1-2 , EN55011 , EN 61000-3-2 EN 61000-3-3
3	Software Validation	ISO 14971 , IEC62304 , IEC60601-1
4	Basic safety & essential performance	IEC 60601-1
5	General requirement & test method	ISO 7494-1
6	Air, Water, suction & wastewater system	ISO 7494-2
7	Dentistry-Patient chair	ISO 6875
8	Basic safety & essential performance of dental equipment	IEC 80 601-2-60
9	Collateral Standard : Usability	IEC 60601-1
10	Usability engineering	IEC 62366
11	Hydraulic motor durability test	ISO 13485
12	Dental Hand piece	ISO 15606
13	Cleaning Validation	ISO 16954 , ISO 19458 , ISO/TS 11080 , ASTM E2871*12
14	Sterilization Validation	ISO 17665-1, ISO/TS 17665-2

8. Summary of clinical testing

No clinical studies are submitted

9. Review

The K3 has the similar device characteristics as the predicate device ; intended use, Power and Utility supply, Syringe, design and use concept are similar. The K3 has a slight difference in components of unit except for curing light. The K3 has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including EMC have been performed to ensure the devices comply with the US regulations. Based on the comparison of intended use and technical features, the K3 is substantial equivalent to the predicate devices.

9. Conclusions

In accordance with the above data and based on the information provided in this premarket notification OSSTEM IMPLANT Co., Ltd. concludes that the K3 is substantially equivalent to predicate devices as described herein.

END