September 4, 2019

Osstem Implant Co., Ltd.
℅ Peter Lee
Special Projects Manager
Hiossen Inc.
85 Ben Fairless Dr
Pennsylvania, Pennsylvania 19030

Re: K183347
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: June 5, 2019
Received: June 6, 2019

Dear Peter Lee:

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,

for Michael Adjodha
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183347

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 device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, 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.
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510(k) Summary

Date Summary Prepared: September 3, 2019

I. Company Information

- Submitter: OSSTEM IMPLANT Co., Ltd.
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  Geumcheon-gu, 08504, Seoul, Korea
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- Correspondent's Name: HIOSSEN Inc.
  85 Ben Fairless Dr. Fairless Hills, PA 19030
  Peter Lee
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II. Device Information

- Trade/Proprietary Name: K3
- Common/Usual Name: Unit, Operative Dental
- Classification Name: Dental Operative Unit and Accessories (per 21 CFR 872.6640)
- Product Code: EIA
- Device Class: Class I

III. Predicate Devices

K3 (K152830)

IV. Product Description

A Dental Unit and Chair K3 (ver 1.2) is designed for dental treatment of children and adults. It is a dental treatment unit in accordance with IEC 80601-2-60. 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 device.

(1) Design Feature

K3, dental operative unit, has features of ergonomic and optimal position for treatment. It consists of adjusted touch panel, 3-way syringe, assistant touch panel, easy opening and closing armrest.

(2) Main Types

There are a couple of types for this device – K3 Mount and K3 Cart which consists of chair, unit, table, seat, stool, 3-way syringe, monitor arms, fool control and console.

(3) Technological Characteristics

K3 is an AC-powered dental operative unit with accessories, intended to supply power to and serve as a base for other dental devices. It includes a treatment chair, dentist element, assistant element and a dental light as offering several additional options and electronically-controlled chair movements with software and water unit functions.

V. Indications for Use

K3 is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.

VI. Summary of Technological Characteristics

The K3 (ver 1.2) functions in a manner similar to and is intended for the same use to the predicate device. Primarily, K3 (ver 1.2) is substantially equivalent to the K3 (K152830) marketed by OSSTEM IMPLANT Co., Ltd and does have some different technological characteristics and slightly different external design. However, these differences do not raise new concerns of substantial equivalence as the performance data and testing of the K3 (ver 1.2) demonstrate that the devices are deemed to be substantially equivalent as described in a following comparison table:

Description	**Subject Device**	**Predicate Device**
Indications for Use	K3 is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.	K3 is intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair.is the dental treatment unit is intended for use in the dental clinic environment and is used by trained dentists and/or dental assistants.
Product Name	K3	K3
Version	1.2	1.1
Code	EIA	EIA
Power & Utility Supply	AC 100-120/220-240V, 50/60Hz, compressed air and water	AC 100-120/220-240V, 50/60Hz, compressed air and water

Main Components	Chair, Unit, Table, Seat, Stool, Monitor Arm*, Hanaro Console* (Note: K3 Cart* model applied ONLY)	Chair, Unit, Table, Seat, Stool, Monitor Arm*, Hanaro Console* (Note: K3 Cart* model applied ONLY)
Syringe	3-way syringe	3-way syringe
Control of water and air	Uses pneumatically controlled vales to water control the flow of air and water. On/off and intensity controlled by foot pedal.	Uses pneumatically controlled vales to water control the flow of air and water. On/off and intensity controlled by foot pedal.
Air Pressure	500kPa(min)/750kPa(max)	500kPa(min)/750kPa(max)
Water Pressure	250kPa(min)/600 kPa(max)	250kPa(min)/600 kPa(max)
Water System	City water supply	City water supply
Water Sanitation System	Distilled water container added	N/A
Suction	HVE (High volume evacuator) Saliva Ejectors	HVE (High volume evacuator) Saliva Ejectors
Patient Load	Max. 135kg	Max. 135kg
Chair Height	Max. 795±10mm, Min. 365±10mm	Max. 790±10mm, Min. 450±10mm
Back Rest	0°±5° to 67°±5°	0° to 66°
Head Rest	-10° to 45°	-10° to 45°
Lift Motor	Hydraulic electromotor	Hydraulic electromotor
Electrical Safety	Complied with IEC 60601-1	Same as
Electromagnetic compatibility	Complied with IEC 60601-1-2	Same as

[Table 1] Comparison between K3 and its predicate device

VII. Principle of Operation

Raising and lowering the dental chair
While the Table Panel or Foot Control's 'Raise' S/W is being operated, the hydraulic motor of the chair operates and the 'Raise' solenoid valve opens, driving the Oil from the Oil Tank to the 'Raise' Cylinder, hydraulically raising the chair. Similarly, while the 'Lower' S/W is being operated, the 'Lower' solenoid valve opens, and the weight of the chair moves the Oil from the 'Raise' Cylinder to the Oil Tank, lowering the chair.

Automatic positioning
Operating the 'Automatic' S/W on the Table Panel commands the chair's control device to automatically move and position the chair and seat to a predetermined position.

Hand-Piece Operation Circuit
Micro S/W, closing the supply air valve and opening the rubber film of the Master Block. Pressing the controller (Foot Control) Pedal at this time opens the supply air valve inside the Table, and the air of the compressor is supplied to the removed Hand-Piece through the distribution block, thereby rotating the Hand-Piece Turbine. The air used to rotate the Hand-Piece Turbine is discharged to the atmosphere through the exhaust pipe.

Vacuum Operation
Removing the Suction from the Holder activates the Sensor mounted inside the Holder, opening the Air

Solenoid Valve and supplying air to the suction device to enable suction.

3-Way Syringe
It operates by air pressure or electronic circuit S/W.

Water Supply System
Upon detection of the cup by the Water Supply Port Sensor, PCB's Volume controls water volume.

Water Tube Cleaning
Pressing the Water Supply Button and Film Viewer Button together after supplying 1.2 L of cleaning solution (2~5% of hydrogen peroxide) to the Water Tube Cleaning/Distilled Water Container activates the Water Tube Cleaning System.

VIII. Non-Clinical Test Data

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 the 3-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)
The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards. 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.

IX. Clinical Test Data

No clinical studies are needed to characterize its performance and establish substantial equivalence.

X. Conclusion

Based upon the above mentioned data and comparison table, the K3 (ver 1.2) is substantially equivalent to the predicate device as described herein.