July 17, 2025

Osstem Implant Company., Ltd. Chair Business
℅ Leszczak Mateusz
Regulatory Affairs Manager
Hiossen Inc.
85 Ben Fairless Dr.
Fairless Hills, Pennsylvania 19030

Re: K251491
Trade/Device Name: K5 Cart, K5 Mount, K5 Swing
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA, KLC
Dated: June 20, 2025
Received: June 20, 2025

Dear Leszczak Mateusz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251491

Please provide the device trade name(s).

K5 Cart, K5 Mount, K5 Swing

Please provide your Indications for Use below.

K5 is intended to supply power to and serve as a base for dental devices and accessories. This product is intended for use by dentist and dental assistance to assist dental treatment of patients for adjusting the position of the patient seat, operating the instruments, and supplying water into the oral cavity through a water line in dental clinical environments.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
K251491

Date: July 16, 2025

1. Company and Correspondent making the submission

- Submitter's Name	:	Osstem Implant Co., Ltd. Chiar Business
- Address	:	192, Haebong-ro, Danwon-gu, Ansan-si, Gyeonggi-do, 15428, Republic of Korea
- Contact	:	Ms. Jimin Hyun
- Phone	:	+82-70-4871-0191
- Correspondent's Name	:	Hiossen Inc.
- Address	:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact	:	Mr. Mateusz Leszczak
- Phone	:	+1-201-266-0657

2. Proposed Device

- Trade or (Proprietary) Name	:	K5 Cart, K5 Mount, K5 Swing
- Classification Name	:	Dental operative unit and accessories
- Regulation Number	:	21 CFR 872.6640
- Devce Classification	:	Class I
- Classification Product Code	:	EIA, KLC

3. Predicated Device

- K5(K233805)

4. Description

The K5 Cart, K5 Mount and K5 Swing are designed for dental treatment and are intended for dental use only and are intended for use by trained medical personnel only.
These devices consist of a foot controller, headrest, backrest, seat, armrest, doctor table, unit, dental light, auxiliary table and doctor stool.
These are 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.

5. Indication for use

K5 is intended to supply power to and serve as a base for dental devices and accessories. This product is intended for use by dentist and dental assistance to assist dental treatment of patients for adjusting the position of the patient seat, operating the instruments, and suppling water into the oral cavity through a water line in dental clinical environments.

6. Comparison of the Indications for Use

Predicated Device : K5 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.

The intended use of the predicated device and the subject device are the same, but more detailed information has been added on how the subject device is used to assist in dental treatment, so there is no effect on substantial equivalence.

7. Summary of Technological Characteristics with predicated device and proposed device

The K5 Cart, K5 Mount, K5 Swing functions in a manner similar to and is intended for the same use to the predicate device. Primarily, K5 Cart, K5 Mount, K5 Swing are substantially equivalent to the K5 (K233805) marketed by OSSTEM IMPLANT Co., Ltd.Chair Business and 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 K5 Cart, K5 Mount, K5 Swing demonstrate that the devices are deemed to be substantially equivalent as described in a following comparison table:

Description	Proposed Devices	Predicate Device	Remark
Indications for Use	The K5 is intended to supply power to and serve as a base for dental devices and accessories. This product is intended for use by dentist and dental assistance to assist dental treatment of patients for adjusting the position of the patient seat, operating the instruments, and suppling water into the oral cavity through a water line in dental clinical environments.	K5 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.	Different
Product Name	K5 Cart, K5 Mount, K5 Swing	K5	Same
510(k) No.	Proposed	K233805	-
Manufacturer	Osstem Implant Co., Ltd. Chair business	Osstem Implant Co., Ltd. Chair business	Same
Product Code	EIA, KLC	EIA, KLC	Same
Model Type	Mount type, Cart type, Swing type	Mount type, Cart type	Different
Unit Type	Single type	Single type	Same
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	Same

Doctor Table	- 3-way syringe - Control of water supply,scaler vibration power, table height, patient position, System Power, Film viewer, Patient Chair Positioning, Light On/Off, Handpiece function, Timer, Mode Selection, LED Display	- : 3-way syringe - Control of water supply,scaler vibration power, table height, patient position, System Power, Film viewer, Patient Chair Positioning, Light On/Off, Handpiece function, Timer, Mode Selection, LED Display	Same
Assist Table	- 3-way syringe, HVE and SE suction - Patient chair positioning , Dental Light on/off, Control of water	- 3-way syringe, HVE and SE suction - Patient chair positioning , Dental Light on/off, Control of water	Same
Main Components	Foot controller, Headrest, Backrest, Seat, Armrest, Doctor Table, Unit, Dental Light, Assistant Table, Doctor Stool, Monitor Arm, Hanaro Console, Joystick Control	Chair, Unit, Table, Seat, Stool, Monitor Arm, Hanaro Console	Same
Syringe	3-way syringe	3-way syringe	Same
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.	Same
Air Pressure	550(min), 600kPa(max)	550(min), 750kPa(max)	Different
Water Pressure	250(min), 600kPa(max)	250(min), 600kPa(max)	Same
Water System	City water supply	City water supply	Same
Water Sanitation System	Distilled water container added	Distilled water container added	Same
Cleaning	Waterline cleaning according to ISO 16954 Waterline: Routine(Daily), Biofilm treatment(2 week) Water Flushing (each patient)	Waterline cleaning according to ISO 16954 Waterline: Routine(Daily), Biofilm treatment(2 week) Water Flushing (each patient)	Same
Warmer	Heating Method : Heating Coil Water Temperature : 25℃~37 ℃ Warmer Volume : 360ml Warmer Power : 300W Warmer input voltage : AC48V	Heating Method : Heating Coil Water Temperature : 25℃~37 ℃ Warmer Volume : 360ml Warmer Power : 300W Warmer input voltage : AC48V	Same
Suction	HVE (High volume evacuator) SE	HVE (High volume evacuator) SE	Same
Patient Load	Max. 150kg	Max. 150kg	Same
Chair Height	Max. 850±30mm, Min. 450±30mm	Max. 840±30mm, Min. 440±30mm	Different
Back Rest	0°±5° to 70°±5°	0°±5° to 70°±5°	Same
Head Rest	-90° to 75°	-90° to 70°	Different
Patient contacting components	Seat: Polyvinyl Chloride Waterline: Polyurethane resins Airline: Polyurethane resins Suction: A16061 3-way syringe: A16061 Warmer: Stainless Steel 304 Water block: C3604	Seat: Polyvinyl Chloride Waterline: Polyurethane resins Airline: Polyurethane resins Suction: A16061 3-way syringe: A16061 Warmer: Stainless Steel 304 Water block: C3604	Same
Principle of Operation	The chair is operated, the rising S/W is activated and the chair is electrically operated. The handpiece is operated, pressing the foot control pedal opens the air supply valve to rotate the handpiece turbine. The 3-way syringe is operated by air	The chair is operated, the rising S/W is activated and the chair is electrically operated. The handpiece is operated, pressing the foot control pedal opens the air supply valve to rotate the handpiece turbine. The 3-way syringe is operated by air	Same

	pressure or electronic circuit S/W	pressure or electronic circuit S/W	
Lift Motor	Electromotor	Electromotor	Same
Dental Light	Available	Available	Same
Foot Control	Standard Wireless	Standard Wireless	Same
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
Electromagnetic compatibility	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same

[Table 1] Comparison between K5 Cart, K5 Mount, K5 Swing and K233805

8. Non-clinical Test Data

Electrical Safety and Electromagnetic compatibility
K5 Cart, K5 Mount, K5 Swing have been verified according to IEC 60601-1, IEC 60601-1-2, IEC 80601-2-60, IEC 60601-1-6 and thus have electrical safety.
Since these standards are verified according to the same standards as the predicated device, their electrical safety is equivalent to that of the predicate device.

Performance test
K5 Cart, K5 Mount, K5 Swing have been verified according to ISO 7494-1, ISO 7494-2, and thus the performance of the product has been demonstrated.
These standards have been verified according to the same standards as predicate devices, so the performance items are equivalent to predicate devices.

Software and System Verification and Validation
The proposed device is identical to the original device in all major software functions, except for the user interface.
The updated software was verified in accordance with IEC 62304 and the FDA Guidance Content of Premarket Submissions for Device Software Functions, so the original device and the submitted device are substantially equivalent, although they have different software versions.

9. Clinical Test Data

Clinical test data is not needed to characterize its performance and establish substantial equivalence.

10. Conclusion

Based upon the above mentioned data and comparison table, the K5 Cart, K5 Mount, K5 Swing are substantially equivalent to the predicate device as described herein.