September 6, 2024

DENTIS CO., LTD.
Kaon Kim
Junior Manager
99, Seongseoseo-Ro, Dalseo-Gu
Daegu, 42718
SOUTH KOREA

Re: K233921
Trade/Device Name: Luvis Chair (LC700C)
Regulation Number: 21 CFR 872.6250
Regulation Name: Dental Chair and Accessories
Regulatory Class: Class I, reserved
Product Code: KLC, EIA
Dated: August 12, 2024
Received: August 12, 2024

Dear Kaon 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 (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233921

Device Name

Luvis Chair (LC700C)

Indications for Use *(Describe)*

Luvis Chair 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.

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510(k) Summary – K233921

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

September 5th, 2024.

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Applicant: DENTIS CO., LTD.
- Address: 99, Seongseoseo-Ro, Dalseo-Gu, Daegu, 42718, Korea, South
- Name of Manufacturer: DENTIS MEDICAL DIVISION
- Address: 6, Yuram-ro, Dong-gu, Daegu, 41065, Korea, South
- Contact Person: Kaon Kim / Junior Manager
- Telephone No.: +82-53-583-2804
- Fax No.: +82-53-583-2806
- Email Address: kaonkim@dentis.co.kr
- Registration No.: 3010373494

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Device Name	Luvis Chair (LC700C)
Regulation Number	21 CFR 872.6640
Common/Usual Name	Dental Unit Chair
Regulatory Class	Class I
Product Code	EIA
Classification Name	unit, operative dental
Panel	Dental

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate and reference devices within this submission are shown as follow;

Predicate device

- 510(k) Number: K183347
- Applicant: Osstem Implant Co., Ltd.
- Device Name: K3
- Regulation Number: 21 CFR 872.6640
- Regulation Name: Dental Operative Unit and Accessories
- Regulatory Class: Class I
- Product Code: EIA
- Classification Name: unit, operative dental

Reference device

- 510(k) Number: K211556
- Applicant: MegaGen Implant Co., Ltd.
- Device Name: N2
- Regulation Number: 21 CFR 872.6640
- Regulation Name: Dental Operative Unit and Accessories
- Regulatory Class: Class I
- Product Code: EIA
- Classification Name: unit, operative dental

The Luvis Chair (LC700C) is substantially equivalent to the predicate devices with respect to intended use, principles of operation, and technological characteristics. The subject device has the same Indications for Use and similar technological characterizes as compared to the predicate and reference devices. Therefore, the Luvis Chair (LC700C) is considered substantially equivalent to the predicate and reference devices.

5. Description of the Device [21 CFR 807.92(a)(4)]

The Luvis Chair (LC700C) includes a chair used by dentists to provide seating for patients during dental procedures. It is designed to position the patient during treatment. The chair consists of a seat, backrest, and armrests that can be adjusted to accommodate the patient's position. Additionally, it may feature a headrest to offer additional support.

Dental unit chairs come equipped with various tools and attachments, including dental lights, suction devices, and air- water syringes. The chair's controls are usually located within reach of the dentist, allowing for quick adjustments during the procedure. The Luvis Chair is intended to supply power to and serve as a base for dental devices and accessories.

[Note] The handpieces and scalers are not included within the scope of this submission. Furthermore, HVE and Saliva Ejector Tips are not included within the scope of the submission.

1) The Luvis Chair (LC700C) is classified as shown below:
LC700C consists of the following:

Model Number	Chair Part	Unit Part	Dr. Table	Assist Table	Foot Controller	Note
		Dental Light: C700	Mount Type			
LC700C	●	●	●	●	●	

2) Description of main components and specifications
The components of the Luvis Chair (LC700C) consist of following items:

Model Number	Parts	Description		Note
LC700C	Chair Part	Chair Part		
	Unit Part	Dental Light	C700	
	Dr. Table	Instrument 1	3-Way Syringe	
		Instrument 2,3 (Air High)	1. Air High Handpiece (*Not included in the submission*)	
		Instrument 4 (Air Low / Elec. Low)	1. Air Low Handpiece (*Not included in the submission*) 2. Elec. Low Handpiece (*Not included in the submission*)	
		Instrument 5 (Scaler)	1. Scaler (*Not included in the submission*)	
	Assist Table	Instrument 1	Dry Air Syringe	
		Instrument 2	3-Way Syringe	
		Instrument 3	HVE	
		Instrument 4	Saliva Ejector	
	Foot Controller	Foot Controller		

6. Indications for Use [21 CFR 807.92(a)(5)]
Luvis Chair 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.

7. Comparison of Technological Characteristics with the Predicate Device

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

Applicant **Device Name**	**DENTIS CO., LTD.** **Luvis Chair (LC700C)**	**Osstem Implant Co., Ltd.** **K3**	**MegaGen Implant Co., Ltd.** **N2**	**SE Note**
	Subject Device	Predicate Device	Reference Device	-
510(k) Number	K233921	K183347	K211556	-
Common/Usual Name	Dental Unit Chair	Unit, Operative Dental	Unit, Operative Dental	-
Regulation Number	21 CFR 872.6640	21 CFR 872.6640	21 CFR 872.6640	-
Product Code	EIA	EIA	EIA	-
Class	Class I	Class I	Class I	-
Model Number	LC700C	K3	N2	-
Indications for Use	Luvis Chair 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 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.	N2 is intended to supply power to and serve as a base for dental devices and accessories. This 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.	Similar
Dentist Element Type (Dr. Table Type)	Mount Type	Mount Type, Cart Type	Mount Type, Cart Type	Similar
Unit Type	Single Type	Single Type	A Type, B Type	Same
Supply Mains	100-120/220-240 Va.c., 50/60 Hz	100-120/220-240 Va.c., 50/60 Hz	100-120/220-240 Va.c., 50/60 Hz	Same
Utility Supply	Compressed air, and Water	Compressed air, and Water	Compressed air, and Water	Same
Main Components	Chair Part, Unit Part, Table(Dr. Table, Assist Table), Chair Seat, Stool, Monitor Arm, Compact Console	Chair, Unit, Table, Seat, Stool, Monitor Arm*, Hanaro Console* (Note: K3 Cart* model applied ONLY)	Chair, Unit, Table, Seat, Stool, Monitor Arm, Operation Table	Similar
Dentist Element (Dr. Table)	1) Accessories: 3-Way Syringe 2) Control of Water Supply, Scaler Vibration Power, Table Height, Patient Chair Positioning, Light On/Off, Handpiece Function, Timer, Mode Selection, LED Display	1) Accessories: 3-Way Syringe 2) 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	1) Accessories: 3-Way Syringe 2) Control of Water Supply, Scaler Vibration Power, Table Height, Patient Chair Positioning, Handpiece Function, Timer, LED Display	Similar

Assist Element (Assist Table)	1) Accessories: Suction (Saliva Ejector, HVE), Dry Air Syringe, 3-Way Syringe 2) Light On/Off, Cup/Spittoon Water Dispenser, Changing the Settings, Position Memories, 1 Person Helper System	1) Accessories: Saliva Ejector (Small, Large), 3-Way Syringe 2) Light On/Off, Cup/Spittoon Water Dispenser, Changing the Settings, Position Memories	1) Accessories: Saliva Ejector, HVE (Small, Large), 3-Way Syringe 2) Second Assi Power Switch, Waterline Power Switch, Control of Water, Light On/Off, Position Memories, Spittoon Wash	Similar
Syringe	Dry Air Syringe, 3-Way Syringe	3-Way Syringe	3-Way Syringe	Similar
Control of Water and Air	Uses pneumatically controlled valves to water control the flow of air and water. On/Off and intensity controlled by foot pedal	Uses pneumatically controlled valves to water control the flow of air and water. On/Off and intensity controlled by foot pedal	Uses pneumatically controlled valves to water control the flow of air and water. On/Off and intensity controlled by foot pedal	Same
Water System	City Water Supply	City Water Supply	City Water Supply	Same
Cleaning	Cleaning method provided for Chair Upholstery, Tray Table, Assist Table, Dr. Table, Spittoon, Suction Filter, Suction(Saliva Ejector, HVE), Dry Air Syringe, 3-Way Syringe, and Waterline	-	Waterline cleaning according to ISO 16954 - Waterline: Routine (Daily) - Shock Treatment (2weeks) Water Flushing (each patient)	
Warmer	Heating Method: Heating Coil Storage Container Temperature: Max. 40℃ Water Temperature: Avg. 33 ~ 35℃ Temperature Sensor: Bi-metallic Thermostats	-	Heating Method: Heating Coil Storage Container Temperature: Max. 40℃ Water Temperature: Avg. 33 ~ 35℃ Temperature Sensor: Bi-metallic Thermostats	
Water Sanitation System	Distilled water container	Distilled water container	Distilled water container	Same
Suction	1) HVE (High Volume Evacuator) 2) Saliva Ejector 3) 1 Person Helper System	1) HVE (High Volume Evacuator) 2) Saliva Ejector	1) HVE (High Volume Evacuator) 2) Saliva Ejector 3) Second Assi	Same
Air Pressure	500kPa(Min) / 750kPa(Max)	500kPa(Min) / 750kPa(Max)	500kPa(Min) / 750kPa(Max)	Same
Water Pressure	215kPa(Min) / 275kPa(Max) (2.5 ± 0.3 kgf/㎠)	250kPa(Min) / 600kPa(Max)	245 kPa(Max)	Similar
Patient Load	Max. 150 kg	Max. 135 kg	Max. 150 kg	Similar
Chair Height	Max. 770±50mm, Min. 480±50mm	Max. 795±10mm, Min. 365±10mm	Max. 700±10mm, Min. 400±10mm	Similar
Back Rest	0°±5° to 65°±5°	0°±5° to 67°±5°	0°±3° to 68°±3°	Similar
Head Rest	Double-articulating headrest First joint: -150˚~+150˚(±5˚) Second joint: -162˚~+174˚(±5˚)	-10 °to 45°	-50° to 14°±2°	Similar
Lift Motor	Hydraulic Electromotor	Hydraulic Electromotor	Hydraulic Electromotor	Same
Dental Light	Available	Available	Available	Same

Foot Control	Available	Available	Available	Same
Electrical Safety	Complied with IEC 60601-1	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	Complied with IEC 60601-1-2	Same
Patient Contacting Components	Seat: Polyvinyl Chloride, Polyester Waterline: Polyurethane, Polyamide 66+ GF25%, Stainless Steel (Chromium plated), C3604 (Chromium plated) Airline: Polyurethane, Polyamide 66+ GF25%, C3604 (Chromium plated), Aluminum Alloy HVE: Aluminum Alloy 3-Way Syringe: C3604 (Chromium plated) Dry Air Syringe: C3604 (Chromium plated) Saliva Ejector: Aluminum Alloy Warmer: Stainless Steel (Chromium Plated)	-	Seat: Polyvinyl Chloride, Polyester Waterline: Polyurethane resin, Polyamide 66+ GF25%, Stainless Steel, C3604, Silicon Airline: Polyurethane, Polyamide 66+ GF25%, Aluminum Alloy HVE: Aluminum Alloy 3-Way Syringe: C3604 (Chromium Plated), Aluminum Alloy Saliva Ejector: Aluminum Alloy Warmer: Stainless Steel 304 (Chromium Plated) Water Block: C3604 (Chromium Plated)	Similar
Principle of Operation	The chair is operated, the rising S/W is activated and the chair is hydraulically 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 pressure or electronic circuit S/W	The chair is operated, the rising S/W is activated and the chair is hydraulically 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 sir pressure or electronic circuit S/W	The chair is operated, the rising S/W is activated and the chair is hydraulically 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 sir pressure or electronic circuit S/W	Similar

b) Substantial Equivalence Discussion

The Luvis Chair (LC700C) is substantially equivalent to the predicate and reference devices identified above with respect to intended use, principles of operation, and technological characteristics. The subject device has the same Indications for Use and similar technological characterizes as compared to the predicate and reference devices. Therefore, the Luvis Chair (LC700C) is considered substantially equivalent to the predicate devices.

8. Non-Clinical Test Summary

The Luvis Chair (LC700C) is verified and validated according to the FDA design control requirements, 21 CFR 820. The subject device had been subjected to the applicable safety and performance testing before release to ensure the device meets all its specifications. The quality assurance measures applied to the design and development of the subject device include, but not limited to risk analysis, verification and validation, product specifications and design reviews.

1) Thermal, electrical, mechanical safety & Electromagnetic Compatibility

The Luvis Chair (LC700C) complies with the electrical safety and electromagnetic compatibility requirements established by the standards below:

- ANSI AAMI ES60601-1 General requirements for basic safety and essential performance
- IEC 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC 80601-2-60 Particular requirements for the basic safety and essential performance of dental equipment

2) Software Validations

The Luvis Chair (LC700C) utilizes original software. The Luvis Chair (LC700C) contains Basic documentation level, and MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance: “Guidance for the Content of Premarket Submissions for Software Functions, issued on June 14, 2023.”

3) Biocompatibility

The biocompatibility evaluation for the Luvis Chair (LC700C) was conducted in accordance with FDA guidance:
- “Guidance for the Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, issued on September 8, 2023”
- ISO 7405 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

The biocompatibility testing included the following tests:
- In vitro cytotoxicity test
- Oral mucosa Irritation test
- Skin sensitization test
- In vitro cytotoxicity test - Agar diffusion method
- In vitro cytotoxicity test - Filter diffusion method

4) Performance Test

The performance test for Luvis Chair (LC700C) was conducted in accordance with the standards below:

- IEC 80601-2-60 Particular requirements for the basic safety and essential performance of dental equipment
- ISO 7494-1 Dentistry - Stationary dental units and dental patient chairs - Part 1: General requirements
- ISO 7494-2 Dentistry - Dental units - Part 2: Air, water, suction and waste water systems

5) Cleaning and Sterilization Validation

Reprocessing validation testing has conducted in accordance with FDA guidance: "Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"

The cleaning and sterilization validation was conducted in accordance with the standards below:

- ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO TS 17665-2 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

Dental unit waterline biofilm treatment testing has conducted in accordance with the standards below:

- ISO 16954 Dentistry - Test methods for dental unit waterline biofilm treatment
- ISO 19458 Water quality - Sampling for microbiological analysis

9. Conclusions [21 CFR 807.92(b)(3)]

In conclusion, the conducted tests, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the Luvis Chair (LC700C) meet applicable requirements and standards. The testing and validation activities conducted demonstrate that any differences between the subject device and the predicate devices do not raise new questions of safety and effectiveness compared to the predicate and reference devices. Therefore, the Luvis Chair (LC700C) is substantially equivalent to the predicate and reference devices.