April 5, 2023

MegaGen Implant Co., Ltd.
Jae Ho Lee
Research Engineer
45, Secheon-ro, 7-gil,
Dasa-eup, Dalseong-gun, Daegu
REPUBLIC OF KOREA

Re: K211556
Trade/Device Name: N2
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA
Dated: March 12, 2023
Received: March 13, 2023

Dear Jae Ho 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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211556

Device Name
N2

Indications for Use *(Describe)*
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.

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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V. 510(k) Summary – K211556

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Date: Apr, 03, 2023

1. Applicant / Submitter

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2. Submission Correspondent

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3. Device

- **Trade Name:** N2
- **Common Name:** Unit, Operative Dental
- **Classification Name:** Dental Operative unit and Accessories
- **Product Code:** EIA
- **Regulation number:** 21 CFR 872.6640
- **Device class: I**

4. Predicate Device

- **510(k) number:** K183347
- **Product name:** K3

5. Description

- **General**
  The N2 is a dental treatment unit tested in accordance with IEC 80601-2-60. This product is used in dentistry only and may only be used by trained medical personnel and trained professional in the field of general dentistry.

- **Technological Characteristics**
  The N2 is an AC-powered dental operative unit with accessories, intended to supply power to and serve as a base for dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. 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.

- **Type**
  The subject device has two types, Cart type and Mount type which consists of chairs, unit, table, seat, stool, 3-way syringe, monitor arm, foot control and console. Each type has Type A and Type B depending on the design of cup filler for filling water and a cuspidor for rinsing the patient's mouth. User can select Type A and Type B.

- **Principle of Operation**
  The chair is operated, the rising S/W is activated and the chair is hydraulically operated.
  The dental device (e.g. 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.

  [Note] The assist device, such as dental handpiece and scaler is not included with this subject device N2. These optional device and accessories are not supplied by manufacturer, and are installed by the end-users using the recommended installation method described in the user manual provided by the manufacturers of these accessories. Also, the HVE Tip and Saliva Ejector Tip are not include with the subject device, N2 and not provided by the manufacturer.

6. Intended Use

The N2 is intended to supply power to and server as a base for dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpiece.

7. Indications for Use

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.

8. Basis for Substantial Equivalence

The N2 is substantially equivalent to the predicate device in terms of intended use, technical & performance characteristic, electrical power, design and function.

Also, the Indications for Use for the subject devices is identical to the primary predicate, K183347.

The performance testing and data performed on the subject device demonstrate that the difference in external design and some technological characteristics compared to the predicate device does not raise any new questions of safety and effectiveness.

Based on the comparison charts below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

	Subject Device	Predicate Device
Manufacturer	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.
510(k) number	K211556	K183347
Indications for Use	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.	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.
Product Name	N2	K3
Product Code	EIA	EIA
Model Type	Mount Type, Cart Type	Mount Type, Cart Type
Unit Type	A type, B type	Sing type
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
Table	- Accessories: 3-way syringe - Control of water supply, scaler vibration power, table height, Patient Chair Positioning, timer, Handpiece function, LED Display	- Accessories: 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
Assist Table	- Accessories: Saliva Ejector, HVE (Small, Large), 3-way Syringe - Second Assi Power Switch, Waterline power switch, Control of water, Light On/Off, Position memories, Spittoon wash	- Accessories: Saliva Ejector (Small, Large), 3-way Syringe - Light On/Off, Cup/ Spittoon water Dispenser, Changing the Settings, Position memories
Main Components	Chair, Unit, Table, Seat, Stool, Monitor Arm, Operation table	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 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.
Water System	City water supply	City water supply
Cleaning	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: Average 33~35℃ Temperature Sensor: Bi-metallic Thermostats	--
Water Sanitation System	Distilled water container added.	Distilled water container added
Suction	HVE (High volume evacuator) Saliva Ejectors	HVE (High volume evacuator) Saliva Ejectors

	Second Assi	
Air Pressure	500kPa(min) / 750kPa(max)	500kPa(min) / 750kPa(max)
Water Pressure	245 kPa(max)	250kPa(min) / 600(kPa)
Patient Load	Max. 150 kg	Max. 135kg
Chair Height	Max. 700±10mm, Min. 400±10mm	Max. 795±10mm, Min. 365±10mm
Back Rest	0°±3° to 68°±3°	0°±5° to 67°±5°
Head Rest	-50° to +14°±2°	-10° to 45°
Rift Motor	Hydraulic electromotor	Hydraulic electromotor
Dental light	Available	Available
Foot control	standard	standard
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1
Electromagnetic Compatibility	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2
Patient contacting components	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)	--
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 air pressure or electronic circuit S/W.

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristics compared to the predicate device for the following:

- Indications for Use, model type, power & utility supply, main components, syringe, control of water and air, water system, water sanitation system, suction, Rift motor, Dental Light, Foot Control, Electrical Safety, Electromagnetic Compatibility, principle of operation, Table Function, Assist Table Function, Warmer specification, cleaning.

2. Differences

The subject device has different characteristics for the following compared to the primary predicate device.

- Water Pressure, Patient Load, Chair Height, Back Rest, Head Rest
  Some technical specifications are different compared to the predicate device, but this does not affect substantial equivalence since these differences only include minor differences in specification ranges.
- Unit Type
  The subject device has the Mount type and Cart Type similar to the predicate device, but each type of

subject device is divided into Type A and Type B depending on the design of cup filler for filling water and a cuspidor for rinsing the patient's mouth.
The unit type of subject device is different compared to the predicate device but this does not affect substantial equivalence since the variety of types widens the range of choices according to user preferences and there is no electrical or performance difference affecting the performance of the device.

- Waterline Cleaning Methods
  Routine (Daily) and shock treatment were performed as recommended by the manufacturer and verified according to ISO 16954.
- Tissue contacting material
  Tissue contacting components were included in biocompatibility tests conducted and there is no affect on biological safety.

3. Discussion

The proposed N2 and predicate device are similar in all the items in the comparison chart except the Water Pressure, Patient Load, Chair Height, Back Rest, Heat Rest, unit type, Waterline Cleaning Methods. These differences do not affect substantial equivalence, also the subject device safety was verified with testing according to IEC 60601-1 and IEC 80601-2-60 for the above differences, the performance test (Bench test) and Waterline Cleaning Validation were also conducted. The test result supports that the subject device is substantially equivalent to the predicate device and the differences do not affect substantial equivalence.
On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the predicate device.

9. Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for N2 components was conducted in accordance with the FDA Guidance Document and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part1: Evaluation and Testing within a Risk Management Process ", as recognized by FDA.
The N2 components are considered surface medical device or external communicating device (intact skin or mucosal membrane) for a duration of less than 24 hours.
The biocompatibility testing was performed for Cytotoxicity, Skin sensitization, Oral Mucosa Irritation or Skin Irritation according to ISO 10993-5 and ISO 10993-10.

Cleaning and Sterilization Validation

A representative sample of the 3-way syringe components were used to validate the cleaning and sterilization. Cleaning of 3-way syringe tip was conducted according to FDA Guidance titled, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling". Sterilization validation testing for steam sterilization by the user has been performed in accordance ISO 17665-1, 2 to verify the sterility assurance level (10^{-6}). The 3-way syringe tip was 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 3-way Syringe can be sterilized to reach an acceptable sterility assurance level.

Cleaning/disinfection validation was conducted on the waterlines of the subject device. Validation was conducted using the following standard:

- ISO 16954:2015 Dentistry-Test methods for dental unit waterline biofilm treatment

Cleaning/disinfection method effectively cleaned the waterline.

Cleaning and Intermediate level disinfection validation was provided representative of all Non-Critical Device components.

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 N2 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 60601-1 was performed. Usability testing was conducted in accordance with Standard EN/IEC 60601-1-6 and EN/IEC 62366.

- IEC 60601-1:2005 + A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 80601-2-60:2012, Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability
- IEC 62366:2015, Medical device- Application of usability engineering to medical devices

Software 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 N2 contains MODERATE level of concern software (firmware). The software was designed and developed according to a software development process and was verified and validated.

Performance Test – Bench Test

The performance tests were conducted as bench test and the test results met the pre-set criteria.

10. Summary of Clinical Testing

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

11. Conclusion

Based upon the mentioned above data and comparison table, the N2 is substantially equivalent to the predicate device as described here in.