November 28, 2023

Osstem Implant Co., Ltd.
% Peter Lee
QA/RA Manager
Hiossen Inc.
85 Ben Fairless Dr.
FAIRLESS HILLS PA 19030

Re: K232012
Trade/Device Name: N1
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: October 25, 2023
Received: October 25, 2023

Dear Mr. 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.

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 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232012

Device Name
N1

Indications for Use *(Describe)*
N1 is a dental portable X-ray imaging system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use N1 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary - K232012

Date: November 26, 2023

1. Company and Correspondent making the submission

- Submitter's Name : Osstem Implant Co., Ltd.
- Address : 2 Floor, B-dong, 51, Mayu-ro 238beon-gil, Siheung-si, Gyeonggi-do, 15079, Republic of Korea
- Contact : Miss. Jimin hyun
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- Correspondent's Name : Hiossen Inc.
- Address : 85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact : Mr. Peter Lee
- Phone : +1-267-759-7031

2. Proposed Device

- Trade or (Proprietary) Name : N1
- Classification Name : Extraoral source x-ray system
- Regulation Number : 21 CFR872.1800
- Devce Classification : Class II
- Classification Product Code : EHD
- 510(K) number : K232012

3. Predicate Device

- Trade or (Proprietary) Name : NOMAD DENTAL X-RAY SYSTEM
- Classification Name : Extraoral source x-ray system
- Regulation Number : 21 CFR872.1800
- Devce Classification : Class II
- Classification Product Code : EHD
- 510(k) number : K051795

4. Description

- N1 is a portable dental X-ray imaging device powered by a rechargeable lithium polymer battery pack. It generates X-rays optimized for dental examinations (on teeth, etc.). The N1's X-ray generator equipped with an X-ray tube consists of control unit, user interface, X-ray aperture (collimator), a back-scatter shielding glass, and remote irradiation switch. The x-ray detectors (digital detectors or analog film) are not accessories for use with the N1. N1 is a product designed to diagnose the conditions of teeth through X-irradiation using its intraoral imaging sensors. Software is included for operation and configuration of the N1. It is of Moderate level of concern and it's not based on the predicate software.

5. Substantial Equivalence Matrix

		Proposed Devices	Predicate Devices	Remark
Device Name		N1	NOMAD DENTAL X-RAY SYSTEM	Different
510(k) No.		Proposed	K051795	Different
Manufacturer		Osstem Implant Co., Ltd.	ARIBEX,INC.	Different
Indications for Use		N1 is a dental portable X-ray imaging system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use N1 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.	The NOMADTM Dental X-ray System is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.	Same
Fixed structure		Handheld device	Handheld device	Same
Remote switch		USB Type-C Cable	N/A	Different
Power		22.2V	14.4V	Similar (included within range of predicate product)
Battery		Rechargeable 22.2V DC Li-ion Polymer Battery Pack	Rechargeable 14.4V DC NiCd battery pack	Different
Tube voltage[kV]		70kV	70kV	Same
Tube current[mA]		3mA	2.3mA	Similar (included within range of predicate product)
X-ray tube	**Focus**	0.3mm	0.4mm	Similar (included within range of predicate product)
	Angle	13’	12’	Similar (included within predicate product)
	Inherent Filtration	0.5mm AI	0.8mm AI	Similar (included within range of predicate product)
	X-ray Coverage (FOV)	20 mm x 30 mm (600 mm²)	Φ 60 mm (2826 mm²)	Similar (included within

		30 mm x 40 mm (1200 mm²)		range of predicate product)
Total filtration		1.5mm Al	1.5mm A1	Same
User		Dentist or Radiologist	Dentist or Radiologist	Same
Operation environment		Dental Clinic	Dental Clinic	Same
Site of application		Tooth	Tooth	Same
Contact area of patient		Buy a sterilized plastic bag at the dental clinic and cover the product with a plastic bag when using	Buy a sterilized plastic bag at the dental clinic and cover the product with a plastic bag when using	Same

6. Indications for Use

- N1 is a dental portable X-ray imaging system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use N1 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

7. Summary of Non-clinical Performance Testing

Software validation and verification test, EMC/Electrical Safety tests, and performance tests were conducted and the test results support that the subject device is substantially equivalent to the predicate device

Non-Clinical Performance Data
We performed the applicable non-clinical tests in the FDA guidance document for solid state x-ray detectors. The digital detectors used for testing are not part of the subject device.

Software Verification and Validation Testing
Software was designed and developed according to a software development process. Also, Software verification and validation test were conducted and documented in accordance with FDA guidance: “The content of premarket submissions for software contained in medical devices, on May 11, 2005”. The software for this device contains “Moderate” level of concern software.

Safety, EMC and Performance Data
N1 complies with the electrical safety and electromagnetic compatibility requirements established by the standards IEC60601-1, IEC60601-1-2, IEC 60601-2-65
The N1 battery has been tested following the standards IEC 62133-2. This successful test results indicate that the lithium battery that operates the N1 system is effective and safe.

8. Summary of Clnical Testing

No clinical studies are submitted.

9. Conclusion

There were some differences in some specifications, but there was no significant difference in the safety / performance of the product, and it was confirmed that the Portable dental X-ray imaging device had better performance than the equivalent device in some specifications.
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this submission, we conclude that the subject device is safe and effective and substantially equivalent to the predicate device.