September 6, 2024

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

Re: K233806
Trade/Device Name: T2 Plus
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: October 17, 2023
Received: November 29, 2023

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 (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233806

Device Name

T2 Plus

Indications for Use *(Describe)*

T2 PLUS is digital X-Ray imaging equipment for dental professionals that converts X-Ray signals into digital signals to acquire 2D images and reconstruct them into 3D images, using Panoramic (PANO), Cephalometric (CEPH), and Computed Tomography (CT) technology for the diagnosis of the anatomical structure of the oral and maxillofacial area. T2-CS-P provides all three modes, whereas T2-C-P provides the first two modes and excludes the CEPH mode. The devices are operated and used by physicians, dentist and X-Ray technicians.

Use is contraindicated for patients with a head circumference of less than 48 cm or those aged 2 years or younger.

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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510(k) Summary

Date: August 05, 2024

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 : Mr. Jinsan Kim
- Phone : +82-70-4871-8968

- 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 : T2 Plus
- Model : T2-C-P, T2-CS-P
- Classification Name : Computed tomography x-ray system
- Regulation Number : 21CFR892.1750
- Devce Classification : Class II
- Classification Product Code : OAS
- Clearance : K233806

3. Predicated Device

- Primary Predicate
  T2-CS, T2-C, Osstem Implant Co., Ltd. (K212303)

4. Description

T2 PLUS is a digital X-ray CT, panoramic, and Cephalo imaging system device composed of X-ray generator, X-ray controller, X-ray supporter, image processing unit (sensor), PC, and software. The apparatus attached to the equipment column is a structure that can be rotated 360 ° by the system control unit. This system control unit actuates the motor control, X-ray generator, and image processing unit (sensor). The height controlling unit controls the column and adjusts the height of the equipment. The X-ray generator and image processing unit (sensor) are attached to the rotating apparatus. When the rotating apparatus starts the rotation, X-ray is irradiated from the X-ray generator (generating unit). This X-ray irradiation penetrates the subject and reaches

the image processing unit (sensor), and then is converted into electric signals to secure imagery information. Inside the imaging section of the image processing unit (sensor), real time X-ray input is converted into electric signals and consecutively combined, resulting in imagery information. The combined panoramic imagery information is then sent to the PC and saved in patient management software

5. Substantial Equivalence Matrix

	Proposed Devices	Predicated Devices	Remark
Device Name	**T2 Plus**	**T2-CS, T2-C**	Different
510(k) No.	K233806	K212303	Different
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Indications for Use	T2 PLUS is digital X-Ray imaging equipment for dental professionals that convert X-Ray signals into digital signals to acquire 2D images and reconstruct them into 3D images, using Panoramic (Pano), Cephalometric (Ceph), and Computed Tomography (CT) technology for the diagnosis of the anatomical structure of the oral and maxillofacial area. T2-CS-P provides all three modes, whereas T2-C-P provides the first two modes and excludes the CEPH mode. The devices are operated and used by physicians, dentist and X-Ray technicians. Use is contraindicated for patients with a head circumference of less than 48 cm or those aged 2 years or younger.	T2 is digital X-Ray imaging equipment for dental professionals that convert X-Ray signals into digital signals to acquire 2D images and reconstruct them into 3D images, using Panoramic (Pano), Cephalometric (Ceph), and Computed Tomography (CT) technology for the diagnosis of the anatomical structure of the oral and maxillofacial area.	Similar (More added explanation of the indication for use)
Perfomance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography	Same
Input Voltage	100-240 VAC	100-240 VAC	Same
Tube Voltage	60-95 kV	60-95 kV	Similar (included within range of predicated product)

Tube Current		1-11 mA	5-11mA	Similar (included within range of predicated product)
Focal Spot Size		0.5mm	0.5 mm	Same
Exposure Time		Max. 22s	Max. 22 s	Same
2D Image Viewing Program		Model Name: 2D02	Model Name: 2D02	Same
3D Image Viewing Program		Model Name: 3D02	Model Name: 3D02	Same
Anatomical Sites		Maxillofacial	Maxillofacial	Same
Image Sensor	**Computed Tomography**	1515DXT EXPD1616P	1515DXT SEN1	Similar (included within range of predicated product)
	Panoramic	1515DXT EXPD1616P	1515DXT SEN1	Similar (included within range of predicated product)
	Cephalometric	XID-C24DC	XID-C24DC	Same
Size of Imaging Volume (cm)		1515DXT : Max. 15x9 EXPD1616P : Max 15x9 (Stiching Mode : Max 15 X 15)	1515DXT : Max. 15x9 SEN1 : Max 15x10 (Stiching Mode : Max 15 X 15)	Similar (included within range of predicated product)
Pixel Resolution	**Computed Tomography**	1515DXT : - 3.94 lp/mm - 1.97 lp/mm EXPD1616P : - 5.1 lp/mm - 2.55 lp/mm	1515DXT : - 3.94 lp/mm - 1.97 lp/mm SEN1 : - 4.0 lp/mm - 2.0 lp/mm	Similar (included within range of predicated product)
	Panoramic	1515DXT : 3.94 lp/mm EXPD1616P : 5.1 lp/mm	1515DXT : 3.94 lp/mm SEN1 : 4.0 lp/mm	Similar (included within range of predicated product)
	Cephalometric	XID-C24DC : 5.0 lp/mm	XID-C24DC : 5.0 lp/mm	Same
Pixel Size	**Computed Tomography**	1515DXT : - 127 ㎛ * 127 ㎛ - 254 ㎛ * 254 ㎛ EXPD1616P : - 98 ㎛ * 98 ㎛ -196 ㎛ *196 ㎛	1515DXT : - 127 ㎛ * 127 ㎛ - 254 ㎛ * 254 ㎛ SEN1 : - 125 ㎛ * 125 ㎛ - 250 ㎛ * 250 ㎛	Similar (included within range of predicated product)

	Panoramic	1515DXT : - 127 ㎛ * 127 ㎛ EXPD1616P : - 98 ㎛ * 98 ㎛	1515DXT : - 127 ㎛ * 127 ㎛ SEN1 : - 125 ㎛ * 125 ㎛	Similar (included within range of predicated product)
	Cephalometric	XID-C24DC - 100 ㎛ * 100 ㎛	XID-C24DC - 100 ㎛ * 100 ㎛	Same
Active Area		[CT] - 1515DXT : 146 x 146 mm - EXPD1616P : 159.5 x 147 mm [Pano] - 1515DXT : 146 x 8.13 mm - EXPD1616P : 159.5 x 7.8 mm [Ceph] - 240 x 4.8 mm	[CT] - 1515DXT : 146 x 146 mm - SEN1 : 160 x 128 mm [Pano] - 1515DXT : 146 x 8.13 mm - SEN1 : 160 x 8 mm [Ceph] - 1.8 x 150 mm	Similar (included within range of predicated product)
DQE		Condition: 0.5 lp/mm [1616P] 76% [1515DXT] 64%	Condition: 0.5 lp/mm [Sen1] 71% [1515DXT] 64%	Similar (included within range of predicated product)
MTF		Condition: 1 lp/mm [1616P] 64% [1515DXT] 56%	Condition: 1 lp/mm [Sen1] 64% [1515DXT] 56%	Similar (included within range of predicated product)
S.E.		The proposed devices and the predicated devices are made with same indications for use, performance, materials, and safety characteristics. Compared to the predicated devices, the proposed devices have different tube voltage, tube current, size of image volume, Pixel Resolution, Pixel Size and Active Area. Most of the differences are all within the scope of the predicated device except for pixel size of computed tomography. The pixel size of computed tomography concerning sensor has the same with predicated deivce and larger pixel output (15 x 15) is possible by the built-in stiching mode of software. ► Therefore, we stated that proposed device(T2-CS-P, T2-C-P) are substantially equivalent to the predicated devices (T2-CS, T2-C) cleared in K212303.	

6. Apllied Standards

Standard Number	Standard Name
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
IEC 60601-1: 2005/AMD1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3:2008/AMD1 2013	Medical electromagnetic equipment- Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-63:2012+A1:2017	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60825-1:2014	Safety of laser products - Part 1: Equipment classification and requirements
IEC 62304: 2006/AMD1 2015	Medical device software – Software life cycle processes
IEC 60601-1-6: 2010+AMD1: 2013 IEC 62366-1: 2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability Medical devices – Application of usability engineering to medical devices
ISO 15223-1:2021	Medical Device-Symbols to be used with medical device label, labelling and information to be supplied – Part 1: General requirements
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
IEC 61223-3-4:2000	Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment
IEC 61223-3-5:2019	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy tests - Imaging performance of computed tomography X- ray equipment
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70kg(150Ib) of Less

7. Applied guideline

- ➔ Electronic Submission Template for Medical Device 510(k) Submissions issued on October2,2023
- ➔ The Special 510(k) Program issued on September 13,2019
- ➔ Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff JUNE 2022
- ➔ Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff NOVEMBER 2017
- ➔ Premarket Assessment of Pediatric Medical Devices Guidance for Industry and FDA Staff MARCH 2014
- ➔ Content of Premarket Submissions for Device Software Functions issued on June 2023
- ➔ Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices issued on September 2016
- ➔ Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions issued on September 2023

8. Indications for Use

T2 PLUS is digital X-Ray imaging equipment for dental professionals that convert X-Ray signals into digital signals to acquire 2D images and reconstruct them into 3D images, using Panoramic (Pano), Cephalometric (Ceph), and Computed Tomography (CT) technology for the diagnosis of the anatomical structure of the oral and maxillofacial area.

T2-CS-P provides all three modes, whereas T2-C-P provides the first two modes and excludes the CEPH mode. The devices are operated and used by physicians, dentist and X-Ray technicians.

Use is contraindicated for patients with a head circumference of less than 48 cm or those aged 2 years or younger.

9. 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.

A study was conducted to assess whether the clinical images from the T2 and T2 Plus devices provide the same diagnostic quality when reviewed by a radiologist.

To demonstrate that the two devices produce images of the same quality, images from

patients of the same gender and similar age group, under identical conditions, were compared. Additionally, both the proposed and predicate devices feature three modes—CT, Pano, and Ceph—each of which was evaluated (CT: 10 cases, Ceph: 10 cases, Pano: 11 cases). A total of 31 cases were reviewed (T2-CS-P: 31 images, T2-CS: 31 images). Questions regarding image quality were conducted to the evaluator to determine their Image is enough to determine diagnose.

Upon reviewing the evaluator' scores, it was confirmed that the scores for each question were identical for both the proposed device and the predicate device. This demonstrates that both devices deliver the same level of performance and quality.

In conclusion, the imaging evaluator confirmed that both the proposed device and the predicate device produce radiological images of adequate quality for dental and orthodontic diagnosis.

This confirmed that the proposed device and the predicate device produce radiological images of equivalent quality, making them suitable for diagnosis.

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
T2 Plus complies with the electrical safety and electromagnetic compatibility requirements established by the standards IEC60601-1, IEC60601-1-2.

10. Summary of Clinical Testing

No clinical studies are submitted.

11. Conclusion

The indication for use and the technical characteristics of the subject device is substantially equivalent to the predicate device. It is substantially equivalent to predicate device in output characteristics and operation mode (CT, Cephalo, Panorama). The major difference is size of image volume however, the non-clinical and clinical study results show that the subject device is substantially equivalent to the predicate device. 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.