September 21, 2021

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

Re: K212303
Trade/Device Name: T2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS,
Dated: July 20, 2021
Received: July 23, 2021

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 (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,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.09.21 09:01:35 -04'00'

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and 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)*
K212303

Device Name
T2

Indications for Use *(Describe)*
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.

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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K212303 - 510(k) Summary

Date: July 20, 2021

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. Jinwoo Bae
- Phone : +82-70-4626-0701

- 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
- Classification Name : X-Ray, Tomography, Computed, Dental
- Regulation Number : 21CFR892.1750
- Devce Classification : Class II
- Classification Product Code : OAS

3. Predicated Device

- Primary Predicate
  T1-CS, T1-C, Osstem Implant Co., Ltd. (K183475)

4. Description

- T2 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**	**T1-CS, T1-C**	Different
510(k) No.	Proposed	K183475	Different
Manufacturer	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Same
Indications for Use	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.	T1-C, T1-CS are are a computed tomography x-ray system intended to produce panoramic, cephalometric or crossectional images of the oral anatomy on a real time basis by computer reconstruction of X-ray image data from the same axial plane taken at different angleds. It provides diagnostic details of the anatomic structures by acquiring 360˚ rotational image sequences of oral and maxillofacial area from a precise treatment planningin adult and pediatric dentistry. The device is operated and used by physicians, dentists, and X-ray technicians.	Same
Perfomance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography	Same
Input Voltage	100-240VAC	100-240 VAC	Same
Tube Voltage	60-95KV	60-100 kV	Similar (included within range of predicated product)
Tube Current	5-11mA	5-16 mA	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: 2D01, 2D02	Similar

				(included within predicated product)
3D Image Viewing Program		Model Name: 3D02	Model Name: 3D01, 3D02	Similar (included within predicated product)
Anatomical Sites		Maxillofacial	Maxillofacial	Same
Image Sensor	**Computed Tomography**	1515DXT SEN1	1515DXT SEN1	Same
	Panoramic	1515DXT SEN1	1515DXT SEN1	Same
	Cephalometric	XID-C24DC	XID-C24DC	Same
Size of Imaging Volume (cm)		1515DXT : Max. 15x9 SEN1 : Max 15x10 (Stiching Mode : Max 15 X 15)	1515DXT : Max. 15x9 SEN1 : Max 15x10	Similar (included within range of predicated product)
Pixel Resolution	**Computed Tomography**	1515DXT : - 3.94 lp/mm SEN1 : - 4.0 lp/mm	1515DXT : - 3.94 lp/mm - 1.97 lp/mm SEN1 : - 4.0 lp/mm - 2.0 lp/mm	Same
	Panoramic	1515DXT : 3.94 lp/mm SEN1 : 4.0 lp/mm	1515DXT : 3.94 lp/mm SEN1 : 4.0 lp/mm	Same
	Cephalometric	XID-C24DC : 5 lp/mm	XID-C24DC : 5 lp/mm	Same
Pixel Size	**Computed Tomography**	1515DXT : - 127 ㎛ * 127 ㎛ SEN1 : - 125 ㎛ * 125 ㎛	1515DXT : - 127 ㎛ * 127 ㎛ - 254 ㎛ * 254 ㎛ SEN1 : - 125 ㎛ * 125 ㎛ - 250 ㎛ * 250 ㎛	Similar (included within range of predicated product)
	Panoramic	1515DXT : - 127 ㎛ * 127 ㎛ SEN1 : - 125 ㎛ * 125 ㎛	1515DXT : - 127 ㎛ * 127 ㎛ SEN1 : - 125 ㎛ * 125 ㎛	Same
	Cephalometric	XID-C24DC - 100 ㎛ * 100 ㎛	XID-C24DC - 100 ㎛ * 100 ㎛	Same
Active Area		[CT] - 1515DXT : 146 x 146 mm - SEN1 : 160 x 128 mm [Pano] - 1515DXT : 146 x 8.13 mm - SEN1 : 160 x 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	Same

	[Ceph] - 1.8 x 150 mm	[Ceph] - 1.8 x 150 mm	

6. Indications for Use

- T2 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.

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.

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

8. Summary of Clnical Testing

No clinical studies are submitted.

9. 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.