August 30, 2019

Osstem Implant Co., Ltd.
% Peter Lee
Official Correspondent
Hiossen Inc.
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K183475
Trade/Device Name: T1-C, T1-CS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: December 13, 2018
Received: December 17, 2018

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183475

Device Name
T1-C, T1-CS

Indications for Use *(Describe)*

T1-C, T1-CS are a computed tomography x-ray system intended to produce panoramic, cephalometric or crosssectional 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 angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and X-ray technicians.

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

(K183475)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Date : 7/31/2019

2. Submitter / Correspondent

Submitter:	OSSTEM IMPLANT Co., Ltd. 2 Floor, B-dong, 51, Mayu-ro 238beon-gil, Siheung-si, Gyeonggi-do, 15079, Republic of Korea Contact: Jiyoon Ha Tel.: +82 70 4394 7809
Correspondent's Name:	HIOSSEN Inc. 85 Ben Fairless Drive, Fairless Hills, PA 19030 Contact: Peter Lee Tel.: 267-759-7031

3. Trade/Proprietary Name:
T1-C, T1-CS

4. Common Name:
Computed tomography x-ray system

5. Classification:
21 CFR 892.1750, Class II
Classification Name: Computed tomography X-ray system
Product Code, OAS

6. Device Description:
"T1-C, T1-CS", a dental radiographic imaging system, consists of three image acquisition modes; panoramic, cephalometric and cone beam computed tomography. Specifically designed for dental radiography of the teeth or jaws, "T1-C, T1-CS" are a complete dental X-ray system equipped with X-ray tube, generator and dedicated detector for dental panoramic, cephalometric and cone beam computed tomographic radiography. The dental CBCT system is based on digital X-ray detector. CT detector is used to capture radiographic diagnostic images of oral anatomy in 3D for dental treatment such as oral surgery or implant. The device can also be operated as the panoramic and cephalometric dental X-ray system based on X-ray detector. T1-CS provides three modes, whereas, T1-C provides only panoramic and cone beam computed tomography mode.

SYSTEM's Key Components:
- SSXI detectors (1515DXT, SEN1, XID-C24DC)
- PC system
  - CPU: Intel i5-4590 3.0GHz
  - RAM: > 8GB
  - Hard disk drive: 256GB (SSD recommended)
  - Graphic board: Nvidia GeForce GTX970
  - Hard disk space: 256GB
- Imaging Software
  - 2D Viewer : Xvision (Model Name : 2D-001), One vision (Model Name : 2D-002)
  - 3D Viewer : OneClinic (Model Name : 3D-001), One 3D (Model Name : 3D-002)

7. Indication for use:

T1-C, T1-CS are a computed tomography x-ray system intended to produce panoramic, cephalometric or crosssectional 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 angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and X-ray technicians.

8. Predicate Device:

Manufacturer: Vatech Co., Ltd
Device Name: PHT-30LFO (Pax-i3D Smart)
Regulation Name: Computed Tomography X-ray System
Classification No.: 21CFR 892.1750, Class II
Product Code: OAS
510(k) Number: K152106

9. Substantial Equivalence:

"T1-CS, T1-C" described in this 510(k) has the similar intended use and technical characteristics as the PHT-30LFO of Vatech Co., Ltd.

Although the detector sizes of our device and the predicate device are different, this difference does not affect the substantially equivalent performance of our device to the predicate, and it does not affect the scope of intended use compared to the predicate device.

Characteristic	**Subject Device** **OSSTEM IMPLANT Co., Ltd.** **T1-CS, T1-C**	**Predicate Device** **Vatech Co., Ltd.** **PHT-30LFO (PaX-i3D Smart)**
510(k) number	K183475	K152106
Indications for Use	T1-C, T1-CS are a computed tomography x-ray system intended to produce panoramic, cephalometric or crosssectional 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 angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and X-ray technicians. T1-CS provides three modes, whereas, T1-C provides only panoramic and cone beam computed tomography mode.	PHT-30LFO is a computed tomography x-ray system intended to produce panoramic, cephalometric or crosssectional 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 angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and X-ray technicians.
Performance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography
Input Voltage	AC 100-240 V	AC 100-240 V
Tube Voltage	60-100 kV	50-99 kV
Tube Current	5 ~16 mA	4 ~16 mA
Focal Spot Size	0.5 mm	0.5 mm
Exposure Time	Max. 22 s	Max. 18 s
Slice Width	0.2-1.0mm	0.1 mm min.

Chin Rest		Equipped Headrest	Equipped Headrest
Mechanical		Compact design	Compact design
2D Image Viewing Program		Model Name: 2D01, 2D02	EasyDent
3D Image Viewing Program		Model Name: 3D01, 3D02	Ez3D Plus
Anatomical Sites		Maxillofacial	Maxillofacial
Image Receptor	**Computed Tomography**	1515DXT SEN1	Xmaru1404CF
	Panoramic	1515DXT SEN1	Xmaru1404CF
	Cephalometric	XID-C24DC	Xmaru2301CF 1210SGA 910SGA Xmaru2301CF-O
Size of Imaging Volume (cm)		1515DXT : Max. 15x9 SEN1 : Max 15x10	Xmaru1404CF : Max. 10x8.5
Pixel Resolution	**Computed Tomography**	1515DXT : - 3.94 lp/mm -1x1 binning - 1.97 lp/mm - 2x2 binning SEN1 : - 4.0 lp/mm - 1x1 binning - 2.0 lp/mm - 2x2 binning	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning
	Panoramic	1515DXT : 3.94 lp/mm SEN1 : 4.0 lp/mm	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning
	Cephalometric	XID-C24DC : 5 lp/mm	Xmaru2301CF : 5 lp/mm 1210SGA : 3.9 lp/mm 910SGA : 3.9 lp/mm Xmaru2301CF-O : 5 lp/mm
Pixel Size	**Computed Tomography**	1515DXT : - 127 ㎛ - 1x1 binning - 254 ㎛ - 2x2 binning SEN1 : - 125 ㎛ - 1x1 binning - 250 ㎛ - 2x2 binning	Xmaru1404CF : - 99 ㎛- 2x2 binning - 198 ㎛- 4x4 binning
	Panoramic	1515DXT : 127㎛ SEN1 : 125 ㎛	Xmaru1404CF : - 99 ㎛- 2x2 binning - 198 ㎛- 4x4 binning
	Cephalometric	XID-C24DC : 100 ㎛	Xmaru2301CF : 100 x 100 ㎛ 1210SGA : 127 x 127 ㎛ 910SGA : 127 x 127 ㎛ Xmaru2301CF-O : 100 x 100
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 **[Ceph]** · 1.8 x 150 mm	**[CT]** · Xmaru1404CF : 135.8 x 36.4 mm **[Pano]** · Xmaru1404CF : 135.8 x 5.94 mm **[Ceph]** · Xmaru2301CF : 5.9 x 230.4 mm · 1210SGA : 260.1 x 325.1 mm

10. Performance Data:

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.

Clinical Performance Data
A clinical study was completed to evaluate the image quality of T1-C, T1-CS's maxillofacial area. The clinical images of patients are presented as the clinical data including date and signature by a licensed professional. The images acquired using T1-C, T1-CS were reviewed by qualified clinicians to be of acceptable clinical effectiveness for the proposed indications for use. The results show that the imaging position, which is different from the one in the predicate device, gives a clinically sufficient image quality.

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
T1-C, T1-CS complies with the electrical safety and electromagnetic compatibility requirements established by the standards IEC60601-1, IEC60601-1-2.

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-3:2008 (Second Edition) + A1:2013 Medical electrical equipment - General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X ray equipment
- IEC 60601-2-63:2012 (First Edition) Medical electrical equipment - Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment - General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC62366:2007 (First Edition) + A1: 2014 Medical devices – Application of usability engineering to medical devices
- Non-Clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Device"
- Testing to confirm compliance with Acceptance Tests

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 active area size, 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.