



Food and Drug Administration
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Vatech Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

October 23, 2015

Re: K152106
Trade/Device Name: PaX-i3D Smart (PHT-30LFO)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: July 24, 2015
Received: July 29, 2015

Dear Mr. Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. Behind the signature, there is a faint, large watermark of the FDA logo.

For

Robert Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics
and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152106

Device Name

PHT-30LFO

PaX-i3D Smart

Indications for Use (Describe)

PHT-30LFO is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional 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.

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Traditional 510(k) Summary

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

Date 510K summary prepared: July 24, 2015

I. SUBMITTER

Submitter's Name : Vatech Co., Ltd.
Submitter's Address: 13, Samsung 1-ro 2-gil, Hwaseong-Si, Gyeonggi-Do, 445-170,
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Submitter's Telephone: +82-31-379-9492
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II. DEVICE

Trade/Proprietary Name: PaX-i3D Smart (PHT-30LFO)
Common Name: Dental Computed Tomography X-ray System
Regulation Name: Computed Tomography X-ray System
Classification: (21CFR 892.1750, Class II)
Product Code: OAS

III. PREDICATE DEVICE

Primary Manufacturer: Vatech Co., Ltd
Device Name: PHT-6500
Regulation Name : Computed Tomography X-ray System
Classification No: 21CFR 892.1750, Class II
Product Code: OAS
510(k) Number: K122606

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

PHT-30LFO, 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, PHT-30LFO is a complete dental X-ray system equipped with x-ray tube, generator and dedicated SSXI detector for dental panoramic, cephalometric and cone beam computed tomographic radiography.

The dental CBCT system is based on CMOS digital X-ray detector. CMOS 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 CMOS X-ray detector.

System's Key Components:

- PHT-30LFO digital x-ray equipment with SSXI detectors (Xmaru1404CF, Xmaru2301CF, Xmaru2301CF-O, 910SGA, 1210SGA)
- PC system
 - CPU: IntelXeon E5-1607 3GHz, 1600 4C or faster
 - RAM: 16GB DDR3-1600 ECC RAM / UDIMM
 - Hard disk drive: 1 TB SATA 1st HDD
 - Graphic board: ZOTAC NVIDIA Geforce GTX 780 Ti AMP! D5 3GB
- Imaging software
 - EasyDent: 2D viewer and patient management software
 - Ez3D Plus : 3D viewer and image analysis software

V. INDICATIONS FOR USE:

PHT-30LFO is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PHT-30LFO dental CBCT system described in this 510(k) has the similar intended use and technical characteristics as the PHT-6500 of Vatech Co.,Ltd.

Characteristic	Proposed Vatech Co., Ltd. PHT-30LFO (PaX-i3D Smart)	Predicate Vatech Co., Ltd. PHT-6500 (PHT-60CFO)
<i>510(k) number</i>	K152106	K122606
<i>Indications for use</i>	PHT-30LFO is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional 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.	PHT-6500 (PHT-60CFO) is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional 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.
<i>Performance Specification</i>	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography
<i>Input Voltage</i>	AC 100-240 V	AC 100-120/200-240 V
<i>Tube Voltage</i>	50-99 kV	50-90 kV

Tube Current		4 ~16 mA	4 ~10 mA
Focal Spot Size		0.5 mm	0.5 mm
Exposure Time		Max. 18 s	0.7 – 24 s
Slice Width		0.1 mm min.	0.1 mm min.
Total Filtration		2.8 mmAl	2.8 mmAl
Chin Rest		Equipped Headrest	Equipped Headrest
Mechanical		Compact design	Compact design
Electrical		LDCP logic circuit	LDCP logic circuit
Software		DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
2D Image Viewing Program		EasyDent	EasyDent
3D Image Viewing Program		Ez3D Plus	Ez3D Plus
Anatomical Sites		Maxillofacial	Maxillofacial
Image Receptor	Computed Tomography	Xmaru1404CF	Xmaru0712CF
			Xmaru1215CF Plus
			Xmaru1215CF Master Plus
	Panoramic	Xmaru1404CF	Xmaru1501CF
	Cephalometric	Xmaru2301CF	Xmaru2301CF
		1210SGA	1210SGA
910SGA		910SGA	
	Xmaru2301CF-O		
Size of Imaging Volume (cm)		Xmaru1404CF : Max. 10x8.5	Xmaru0712CF : Max. 8x8
			Xmaru1215CF Plus : Max. 12x9
			Xmaru1215CF Master Plus : Max. 12x9
Pixel Resolution	Computed Tomography	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning	Xmaru0712CF : 3.5 lp/mm
			Xmaru1215CF Plus : 3.5 lp/mm
Xmaru1215CF Master Plus : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning			
	Panoramic	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning	Xmaru1501CF : 5 lp/mm

	<i>Cephalometric</i>	Xmaru2301CF : 5 lp/mm	Xmaru2301CF : 5 lp/mm
		1210SGA : 3.9 lp/mm	1210SGA : 3.9 lp/mm
		910SGA : 3.9 lp/mm	910SGA : 3.9 lp/mm
		Xmaru2301CF-O : 5 lp/mm	
<i>Pixel Size</i>	<i>Computed Tomography</i>	Xmaru1404CF : - 99 μm - 2x2 binning - 198 μm - 4x4 binning	Xmaru0712CF : 140 x 140 μm
			Xmaru1215CF Plus : 140 x 140 μm
			Xmaru1215CF Master Plus : - 99 μm - 2x2 binning - 198 μm - 4x4 binning
	<i>Panoramic</i>	Xmaru1404CF : - 99 μm - 2x2 binning - 198 μm - 4x4 binning	Xmaru1501CF: 100 x 100 μm
	<i>Cephalometric</i>	Xmaru2301CF : 100 x 100 μm	Xmaru2301CF : 100 x 100 μm
		1210SGA : 127 x 127 μm	1210SGA : 127 x 127 μm
		910SGA : 127 x 127 μm	910SGA : 127 x 127 μm
		Xmaru2301CF-O : 100 x 100 μm	

VII. PERFORMANCE DATA

Summary of Performance Testing:

The PHT-30LFO dental CBCT system described in this 510(k) is similar to the predicate device in its indications for use, materials, safety characteristics, X-ray source.

Moreover, the following information further substantiates the substantial equivalence between two devices:

The fundamental technological characteristics of the subject and predicate device are similar.

Laboratory and clinical performance testing using the same test protocols as used for the cleared detectors was evaluated by qualified individuals employed by the sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

For both devices, the differences are as follows.

1. *Xmaru1404CF*, a new SSXI detector for PHT-30LFO, has a different active area compared to *Xmaru2301CF* of PHT-6500 (K122606), the predicate device. Also the subject device offers *Xmaru2301CF-O* which has different data output interface compared with the *Xmaru2301CF* of PHT-6500 (K122606).

2. *Change to Free Input Voltage: For the predicate device, changing the input voltage from 110V to 230V would require A separate tools and electrical work whereas the new device is equipped with a new power board which is capable of handling the input power between 100 V and 240 V without a separate tool or electrical modification.*
3. *The CBCT reconstruction algorithm for the subject device is different from the predicate device.*

Non-clinical test and clinical consideration test were conducted for the PHT-30LFO system's new sensor and compared with the predicate device with regard to Modulation Transfer Function (MTF), Detective Quantum Efficiency (DQE) and Noise to Power Spectrum (NPS).

Based on Non-Clinical Test results of the new detector Xmaru1404CF of the subject device, the measured pixel sizes of the new sensor (Xmaru1404CF) are very similar to that of the predicate device (Xmaru1215CF Master Plus). Therefore, compared to the predicate device, the test patterns of the new sensor images show the test subjects without aliasing phenomenon throughout the same spatial frequency as the predicate device. Moreover, the new Xmaru1404CF sensor has performed similarly or better than the predicate device in terms of the overall DQE performance, given the DQE variation in low frequency (~ 0.5 lp/mm). The new sensor also exhibits consistently better performances in terms of MTF and NPS.

For the new detector Xmaru2301CF-O of PHT-30LFO, the Non-Clinical test results demonstrated the same characteristics in terms of MTF, NPS, and DQE performance compared to Xmaru2301 CF detector of the predicate device. The change in the data output interface has not caused any changes in the performance or the level of artifacts. All performance parameters for both detectors have shown similar results.

In conclusion, the diagnostic image quality of the new sensor is equal or better than those of the predicate device and there is no significant difference in efficiency and safety.

The CBCT image reconstruction for PHT-30LFO applies iterative reconstruction algorithm for the reduction of noise in the CT image capture mode. Iterative reconstruction algorithm reconstructs raw data from the PHT-30LFO dental CBCT system to produce images containing noise levels less than or equal to images produced by standard filtered back projection reconstruction.

In addition to non-clinical tests, clinical images generated from the subject device were compared to

a group of images taken from the predicate devices to provide further evidence in addition to the laboratory performance data to show that the complete system works as intended and to establish substantial equivalence based on the modifications to the device.

Software Verification and Validation Testing

Software verification and validation tests were conducted and documented 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 software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.

The predicate device and the proposed device utilize the identical image viewing software.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(Ed. 3, 2005), IEC 60601-1-3 (Ed. 2, 2008), IEC 60601-2-63 (Ed. 1, 2012) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review.

PHT-30LFO meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical & Clinical considerations according to FDA Guidance “Guidance for the submissions of 510(k)’s for Solid State X-ray Imaging Devices” were performed.

Bench testing according to FDA Guidance “Format for Traditional and Abbreviated 510(k)s, section 18, Performance Testing – Bench” were performed.

Acceptance test and CT image evaluation report according to IEC 61223-3-4 and IEC 61223-3-5 were performed.

All test results were satisfactory.

VIII. CONCLUSIONS

The proposed device and the predicate device have the same indications for use and demonstrate the similar technical characteristics. As demonstrated in the non-clinical and clinical considerations, the new detectors performed similar or better than the predicate device in various performance parameters such as DQE, MTF and NPS. The risks of different voltage requirement of the new device is evaluated and mitigated in electrical safety test, EMC test. The functionality and safety of the new iterative reconstruction algorithm for the CT capture mode were assured by the company procedures that conform to accepted practices. Quality assurance procedures are adhered to, and meeting the specifications and functional requirements is demonstrated via testing.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that PHT-30LFO is safe and effective and substantially equivalent to the predicate device as described herein.

END