K122606

NOV 20 2012

Special 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: August 23rd, 2012

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Vatech Co., Ltd.
Submitter's Address:	23-4, Seogu-Dong, Hwaseong-Si, Gyeonggi-Do, 445-170, Republic of Korea
Submitter's Telephone:	+82-31-379-9585
Contact person:	Mr. Sung-Hee Park
Official Correspondent: **(U.S. Designated agent)**	Dave Kim (davekim@mtech-inc.net)
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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/Proprietary Name:	PHT-6500 (PHT-60CFO)
Common Name:	Dental Computed Tomography X-ray System
Classification Name:	System, X-ray, Tomography, Computed , Dental(21CFR 892.1750, Class II)
Product Code:	OAS

Predicate Device:

Manufacturer:	Vatech Co., Ltd
Device Name:	PaX-Flex3D (PHT-7000)
510(k) Number:	K121412

Device Description:

PHT-6500 (PHT-60CFO), a dental radiographic imaging system, consists of three different image acquisition modes; panoramic, cephalometirc and cone beam computed tomography. Specifically designed for dental radiography of the teeth or jaws, PHT-6500 (PHT-60CFO) 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.

Indication for use:

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.

Summary of the technological characteristics of the device compared to the predicate device:

PHT-6500 (PHT-60CFO) described in this special 510(k) submission is substantially equivalent to PaX-Flex3D (K121412) and has the same indications for use and similar technical characteristics as PaX-Flex3D (PHT-7000) of Vatech Co., Ltd. Table 1 summarizes the technological characteristics of the PHT-6500 (PHT-60CFO) vs. the predicate device

Table 1. Comparison of PCH-2500 (PaX-i) and PCH-2500 (K113672)

Characteristic	**Proposed** **Vatech Co., Ltd.** ***PHT-6500 (PHT-60CFO)***	**Predicate** **Vatech Co., Ltd.** ***PaX-Flex3D (PHT-7000)***
510(k) number	-	K121412
Indications for use	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.	PaX-Flex3D (PHT-7000) 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.
Performance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography
Input Voltage	AC 100-120/200-240 V	AC 100-120/200-240 V
Tube Voltage	50-90 kV	50-90 kV
Tube Current	4 ~10 mA	2 ~10 mA
Focal Spot Size	0.5 mm	0.5 mm
Exposure Time	0.7 – 24 s	1.9 – 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
Anatomical Sites	Maxillofacial	Maxillofacial

Image Receptor		***Computed Tomography*** *(Flat Panel Detector)*		Xmaru0712CF	Xmaru0712CF
				Xmaru1215CF Plus	Xmaru1215CF Plus
				Xmaru1215CF Master Plus	-
		Panoramic *(CMOS photodiode array)*		Xmaru1501CF	Xmaru1501CF
		Cephalo Metric *(CMOS photo diode array)*	*Scan Type*	Xmaru2301CF	Xmaru2301CF
			One Shot Type	1210SGA	-
				910SGA	-
Size of Imaging Volume		***Xmaru0712CF***		Max. 8 x 8 cm	5 x 5 cm / 8 x 5 cm / 8 x 8 cm
		Xmaru1215CF Plus		Max.12 x 9 cm	5 x 5 cm / 8 x 5 cm / 8.5 x 8.5 cm /12 x 8.5 cm
		Xmaru1215CF Master Plus		Max.12 x 9 cm	-
Pixel Resolution	***CT***	***Xmaru0712CF***		3.5 lp/mm	3.5 lp/mm
		Xmaru1215CF Plus		3.5 lp/mm	3.5 lp/mm
		Xmaru1215CF Master Plus		10.1 lp/mm - full resolution 5.0 lp/mm - 2x2 binning 2.5 lp/mm - 4x4 binning	-
	Pano	***Xmaru1501CF***		5 lp/mm	5 lp/mm
	Ceph	***Xmaru2301CF***		5 lp/mm	5 lp/mm
		910SGA		3.9 lp/mm	-
		1210SGA		3.9 lp/mm	-
Pixel Size	***CT***	***Xmaru0712CF***		140 x 140 ㎛	140 x 140 ㎛
		Xmaru1215CF Plus		140 x 140 ㎛	140 x 140 ㎛
		Xmaru1215CF Master Plus		49.5 ㎛ - full resolution 99 ㎛ - 2x2 binning 198 ㎛ - 4x4 binning	-
	Pano	***Xmaru1501CF***		100 x 100 ㎛	100 x 100 ㎛
	Ceph	***Xmaru2301CF***		100 x 100 ㎛	100 x 100 ㎛
		910SGA		127 x 127 ㎛	-
		1210SGA		127 x 127 ㎛	-

Summary of Performance Testing:

Indications for use, safety characteristics, and non-clinical performance for panoramic, cephalometric and CBCT sensors of PHT-6500 (PHT-60CFO) and PaX-Flex3D (PHT-7000) are similar. The primary differences are as follows: PHT-6500 (PHT-60CFO) introduces one new cone beam CT sensor, Xmaru1215CF Master Plus, and two new cephalo sensors (One Shot type), 910SGA and 1210SGA. The non-clinical performance and clinical consideration report for the new SSXI sensors are provided separately in this submission. Based on the non-clinical and clinical consideration and the outcome of a comparative review by a licensed dentist of images from both devices, PHT-6500 (PHT-60CFO) is substantially equivalent, in terms of safety and effectiveness, with PaX-Flex3D (PHT-7000), the predicate device.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (2001), IEC 60601-1-3 (Ed. 1, 1994), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed. 1, 1993), IEC 60601-2-32 (Ed. 1, 1994) and IEC 60601-2-44 (Ed. 2, 2002) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

PHT-6500 (PHT-60CFO) 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.
Acceptance test according to IEC 61223-3-4 and IEC 61223-3-5 was performed.
All test results were satisfactory.

Conclusion:

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-6500 (PHT-60CFO) is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO-66
Silver Spring, MD 20993-002

November 20, 2012

Vatech Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberley Lane
HOUSTON TX 77079

Re: K122606
Trade/Device Name: PHT-6500 (PHT-60CFO)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: October 22, 2012
Received: October 25, 2012

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.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K122606

Device Name: PHT-6500 (PHT-60CFO)

Classification: System, X-ray, Tomography, Computed, Dental
(21 CFR 892.1750, Product Code OAS, Class II)

Indications for Use:

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..

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2012.11.20 15:36:58 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____**K122606**_____