K130585

JUL 15 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date 510K summary prepared : February 28, 2013

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
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(U.S. Designated agent)	
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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:	PCH-2500
Common Name:	Digital X-ray Imaging System
Classification Name:	System, X-Ray, Extra oral Source, Digital (21CFR 872.1800, class II)
Product Code:	MUH

Predicate Device:

Manufacturer:	Vatech Co., Ltd
Device Name:	PCH-2500
510(k) Number:	K130585

Description:

PCH-2500 is a dental digital radiographic imaging system which is available in two different image acquisition modes. Specifically designed for dental radiography of the teeth or jaws, PCH-2500 can be equipped with four dedicated sensors for two different X-ray modalities : one panoramic (Xmaru1501CF), two cephalometric scan type (Xmaru2301CF and Xmaru3001CF) and three flat panel one shot ceph sensors (1210SGA, 910SGA and 1417PGA). The proposed device is available with two X-ray generator options.

PCH-2500 offers the digital panoramic and cephalometric X-ray modality for dental radiographs. The multi platforms of PCH-2500 imaging mode provides a wide range of imaging options based on the patient diagnostic needs.

Indication for use:

PCH-2500 is a digital extra oral source x-ray system intended to take panoramic and cephalometric images of the oral and maxillofacial anatomy to provide diagnostic information for adult and pediatric patients. The device should be operated and used by dentists, x-ray technicians and other professionals licensed by the law of the state in which the device is used.

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

The new device described in this Traditional 510(k) submission is an upgraded version of the predicate device with the same model name, the same indications for use and technical characteristics. Table 1 summarizes the technological characteristics of the new vs. the predicate device.

Table 1. Comparison of new PCH-2500 and the predicate device

Characteristic	Proposed Vatech Co., Ltd. PCH-2500	Predicate Vatech Co., Ltd. PCH-2500
510(k) number	K130585	K122155, dated on 10/4/2012
Indications for use	PCH-2500 is a digital extra oral source x-ray system intended to take panoramic and cephalometric images of the oral and maxillofacial anatomy to provide diagnostic information for adult and pediatric patients. The device should be operated and used by dentists, x-ray technicians and other professionals licensed by the law of the state in which the device is used.	PCH-2500 is a digital extra oral source x-ray system intended to take panoramic and cephalometric images of the oral and maxillofacial anatomy to provide diagnostic information for adult and pediatric patients. The device should be operated and used by dentists, x-ray technicians and other professionals licensed by the law of the state in which the device is used.
Performance Specification	Panoramic and cephalometric	Panoramic and cephalometric
Input Voltage	AC 100-240 V	AC 100-120 / 200-240 V
Tube Voltage	50-99 kV	50-90 kV
Tube Current	4 ~16 mA	4 ~10 mA
Exposure Time	Max. 20.2 s	Max. 20.2 s

X-ray Source		D-052SB OPX/105	D-052SB
X-ray Generator		DG-07D11T2 (for D-052SB) DG-07D11C1 (for OPX/105)	HDG-07B10T2
Focal Spot Size		0.5 mm	0.5 mm
Slice Width		0.1 mm min.	0.1 mm min.
Total Filtration		Min. 2.8 mmAl	Min. 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
Anatomical Sites		Maxillofacial	Maxillofacial
Image Receptor	panoramic (CMOS photodiode array)	Xmaru1501CF	Xmaru1501CF
	Cephalometric (CMOS photodiode array)	Xmaru2301CF	Xmaru2301CF
		Xmaru3001CF	-

	Cephalometric (Amorphous silicon TFT with scintillator)	1210SGA	1210SGA
		910SGA	910SGA
		1417PGA	-
Pixel Resolution	Xmaru1501CF	5 lp/mm	5 lp/mm
	Xmaru2301CF	5 lp/mm	5 lp/mm
	Xmaru3001CF	5 lp/mm	-
	1210SGA	3.9 lp/mm	3.9 lp/mm
	910SGA	3.9 lp/mm	3.9 lp/mm
	1417PGA	3.9 lp/mm	-
Pixel Size	Xmaru1501CF	100 x 100 μm	100 x 100 μm
	Xmaru2301CF	100 x 100 μm	100 x 100 μm
	Xmaru3001CF	100 x 100 μm	-
	1210SGA	127 x 127 μm	127 x 127 μm
	910SGA	127 x 127 μm	127 x 127 μm
	1417PGA	127 x 127 μm	-

Summary of Performance Testing:

The PCH-2500 dental digital radiographic imaging system described in this 510(k) is identical to the predicate device in its indications for use, performance, materials, safety characteristics, image viewing program and accessory components

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

- The fundamental technological characteristics of the subject and predicate device were the same.
- 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.
- The intended use of the modified device, as described in the labeling, has not changed as a result of the labeling modification(s).

For both devices, the differences are as follows.

1. New SSXI detectors, 1417PGA (One Shot Ceph mode) and Xmaru3001CF (Scan Ceph mode) for the newly upgraded PCH-2500 have different active areas compared with k122155, the predicate device.

2. Change to Free Input Voltage: For the predicate device, changing the input voltage from 110V to 200V would require separate tools and electrical works whereas the new device is equipped with a newly designed 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 proposed PCH-2500 is available with two different X-ray generator options. To evaluate the safety, safety test is conducted for each generator according to the IEC Standard. Moreover, separate image evaluation is performed for each X-ray generator which is considered as one of critical components affecting the quality of radiographic images and imaging performance of the device.

4. For proposed PCH-2500, a new generator for X-ray tube has the capacity to generate more tube current and tube voltage than the predicate device. Moreover, the maximum irradiation condition for each capture mode is defined differently by diversifying the operating range of the generator specifications.

The non-clinical performance (including MTF, DQE, NPS test) and clinical consideration report for the new image receptor, Xmaru3001CF and 1417PGA, are provided separately in this submission. Based on the non-clinical and clinical consideration and the outcome of an expert review of image comparisons for both devices, we can claim the substantial equivalence of PCH-2500 in comparison with its predicate device, PCH-2500(K122155), in terms of safety and effectiveness.

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 (2000), IEC 60601-1-3 (1994), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed. 1, 1993) and IEC 60601-2-32 (Ed. 1, 1994) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2 (2007).

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

PCH-2500 also 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. For clinical consideration, separate clinical image evaluation is performed for each X-ray generator which is considered as one of critical components affecting the quality of radiographic images of the device.

Acceptance test according to IEC 61223-3-4 was performed. The separate imaging evaluation is performed for each X-ray generator which is considered as one of critical components affecting the imaging performance of the device.

DICOM Conformance Statement, image viewing SW validation reports, biocompatibility evaluation report and nonclinical consideration for detectors same with predicate device are not provide in this submission, because DICOM standard

conformance, accessory components, image viewing program and the detectors between proposed and predicate device are same.

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 PCH-2500 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 – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2013

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

Re: K130585
Trade/Device Name: PCH-2500
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: June 7, 2013
Received: June 11, 2013

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
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): K130585

Device Name: PCH-2500

Indications for Use:

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Prescription Use √ 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)

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

510(k) K130585