Special 510(k) Summary

SEP 4 2012

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

Date

7/13/2012

Manufacturer

Vatech Co., Ltd.
23-4, Seogu-Dong, Hwaseong-Si, Gyeonggi-Do, 445-170, Korea Republic

Tel: +82-31-379-9585
Fax: +82-31-379-9638
Contact person: Mr. Sung-Hee Park

Official Correspondent (U.S. Designated agent)

Dave Kim / Mtech Group
12946 Kimberley Ln, Houston, TX 77079
Tel: +713-467-2607
Fax: +713-464-8880
Contact person: Mr. Dave Kim (davekim@mtech-inc.net)

Trade/Proprietary Name:

PCH-2500 (PaX-i)

Common Name:

Digital X-ray Imaging System

Classification Name:

System, X-Ray, Extra oral Source, Digital (21CFR 872.1800, Product code MUH, class2)

Description:

PCH-2500 (PaX-i) 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-(PaX-i) can be equipped with four dedicated sensors for two different X-ray modalities : one panoramic (Xmaru1501CF), one cephalometric scan type (Xmaru2301CF) and two flat panel one shot ceph sensors (1210SGA and 910SGA).

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

Indication for use:

PCH-2500 (PaX-i) 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.

Predicate Device:

Manufacturer	: Vatech Co., Ltd
Device	: PCH-2500
510(k) Number	: K113672 (Decision Date – 3/27/2012)

Substantial Equivalence:

PCH-2500 (PaX-i) described in this special 510(k) submission has the same indications for use and similar technical characteristics as PCH-2500 (K113672) of Vatech Co., Ltd.

Characteristic	Proposed Vatech Co., Ltd. PCH-2500 (PaX-i)	Predicate Vatech Co., Ltd. PCH-2500
510(k) number	-	K113672, dated on 3/27/2012
Indications	PCH-2500 (PaX-i) is a digital	PCH-2500 is a digital extra

for use	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.	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 100-120 / 200-240 V	AC 100-120 / 200-240 V
Tube Voltage	50-90 kV	50-90 kV
Tube Current	4-10 mA	4-10 mA
Focal Spot Size	0.5 mm	0.5 mm
Exposure Time	Max 20.2 s	Max 20.2 s
Total Filtration	2.8 mmAl	2.8 mmAl
Pixel Resolution	Xmaru1501CF panoramic sensor : 5 lp/mm	Xmaru1501CF panoramic sensor : 5 lp/mm
	Xmaru2301CF cephalometric (scan type) : 5 lp/mm	Xmaru2301CF cephalometric (scan type) : 5 lp/mm
	1210SGA cephalometric (one shot type) : 3.9 lp/mm	1210SGA cephalometric (one shot type): 3.9 lp/mm
	910SGA cephalometric (one shot type) : 3.9 lp/mm	

Pixel Size	Xmaru1501CF panoramic sensor : 100 x 100 μm	Xmaru1501CF panoramic sensor : 100 x 100 μm
	Xmaru2301CF cephalometric (scan type): 100 x 100 μm	Xmaru2301CF cephalometric (scan type): 100 x 100 μm
	1210SGA cephalometric (one shot type) : 127 x 127 μm	1210SGA cephalometric (one shot type) : 127 x 127 μm
	910SGA cephalometric (one shot type) : 127 x 127 μm	
Image Receptor	CMOS photodiode array – panoramic (Xmaru1501CF) & cephalometric (Xmaru2301CF) Amorphous silicon TFT with scintillator – Cephalometric (1210SGA, 910SGA)	CMOS photodiode array – panoramic (Xmaru1501CF) & cephalometric (Xmaru2301CF) Amorphous silicon TFT with scintillator – Cephalometric (1210SGA)

Indications for use, safety characteristics, and non-clinical performance for panoramic and cephalometric sensors of PCH-2500 (PaX-i) and PCH-2500 are identical. The primary differences are as follows: PCH-2500 (PaX-i) offers a new solid state X-ray sensor for cephalometric mode: 910SGA. The non-clinical performance and clinical consideration report for the new SSXI detector, 910SGA, 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 (PaX-i) in comparison with its predicate device, PCH-2500, 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 (2001),. IEC 60601-1-3 (Ed. 1, 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.

PCH-2500 (PaX-i) 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.

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 PCH-2500 (PaX-i) 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 Room – WO66-G609
Silver Spring, MD 20993-0002

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

SEP 4 2012

Re: K122155
Trade/Device Name: PCH-2500 (PaX-i)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH and MQB
Dated: August 21, 2012
Received: August 23, 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

Enclosure

Indications for Use

510(k) Number(if known): ~~K132155~~ K122155

Device Name: PCH-2500 (PaX-i)

Classification: System, X-Ray, Extraoral Source, Digital
(21 CFR 872.1800, Product code MUH, Class2)

Indications for Use:

PCH-2500 (PaX-i) 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, and x-ray technicians and other professionals licensed by the law of the state in which the device is used.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of Radiological Devices
DIVD
510(k) 5122155

Concurrence of CDRH, Office of Device Evaluation(ODE)