

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

January 18, 2010

Manufacturer

Vatech Co., Ltd.

23-4, Seogu-Dong, Hwaseong-Si, Gyeonggi-Do, 445-170, Korea Republic

Tel: +82-31-679-2081

Fax: +82-31-379-9587

Contact person: Mr. Choi Hyuk-jun

United States Sales Representative (U.S. Designated agent)

E-WOO Technology USA Inc.

256 North Sam Houston Pkwy E. #115, Houston, TX 77060, USA

Tel: +281-598-8124

Fax: +281-598-8150

Contact person: Mr. Dave Kim

Trade/Proprietary Name:

PaX-Primo

Common Name:

Digital X-ray Imaging System

Classification Name:

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

Description:

PaX-Primo diagnostic equipment is a dental panoramic X-ray system which consists of X-ray generator, X-ray controller, X-ray beam limiting device, image process unit and exposure switch. This device utilizes a high voltage generator to generate X-ray by inputting energy to the anode and the cathode. The X-ray is exposed on the oral maxillofacial area of a patient before reaching CMOS digital sensor. The CMOS sensor converts resulting X-ray into electrical charge. The electrical pattern is further converted to voltage and a digital signal which is interpreted by a computer to produce a digital image.

Indication for use:

PaX-Primo is a digital panoramic dental X-ray Imaging system that uses a CMOS detector for real time digital image acquisition. It is intended for producing diagnostic X-ray radiographic images of skull, dentition, and oral structures. The device is operated and used by physicians, dentists and X-ray technologists.

Predicate Device:

Manufacturer : Vatech Co., Ltd.
 Device : PaX-P&P
 510(k) Number : K073365 (Decision Date - Apr. 8. 2008)

Substantial Equivalence:

The PaX-Primo described in this 510(k) has the same intended use and similar technical characteristics as the PaX-P&P of Vatech Co., Ltd.

Characteristic	Proposed Vatech Co., Ltd. PaX-Primo	Predicate Vatech Co., Ltd. PaX-P&P
510(k) number	-	K073365
Indications for use	PaX-Primo is a digital panoramic dental X-ray Imaging system that uses a CMOS detector for real time digital image acquisition. It is intended for producing diagnostic X-ray radiographic images of skull, dentition, and oral structures. The device is operated and used by physicians,	PaX-P&P is a digital x-ray system that uses a high resolution CCD detector for real time digital image acquisition. The system allows lower radiation dose, simple use interface, and produces high quality images. It is intended for producing diagnostic X-ray radiographic images of skull, dentition,

	dentists and X-ray technologists.	and orla structures. The device is operated and used by physicians, dentists, and x-ray technologist.
Performance Specification	Panoramic	Panoramic
Power source	110V/230V~, 50/60Hz	110V/230V~, 50/60Hz
X-ray tube	D-051 (Toshiba)	D-051 (Toshiba)
Focal spot size	0.5 mm	0.5 mm
Total filtration	2.8 mm Al	2.8 mm Al
Tube voltage	50 – 80 kVp	50 – 80 kVp
Tube current	2 – 10 mA	2 – 10 mA
Nominal magnification	1.3	1.3
Exposure time	Min. 6.5 sec Max. 13.5 sec	Min. 6.6 sec Max. 13.2 sec
DICOM compatibility	Compatible	Compatible
X-ray beam	Fan beam	Fan beam
Pixel size	0.100 mm	0.096 mm
Active area	150.4x6 mm	146x6 mm

The indications for use, material, form factor, performance, and safety characteristics between PaX-Primo and the predicate device are the same. The primary difference is cosmetic, structure and component used only. Accordingly we can claim the substantial equivalence of PaX-Primo to the predicate device.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32 was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

Non-clinical & Clinical considerations according to FDA Guidance “Guidance for the Submissions of 510(k)’s for Solid State X-ray Imaging Devices” 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 PaX-Primo 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

AUG 21 2013

VATECH Co., Ltd.
% Mr. Dave Kim
Product Compliance Officer
E-WOO Technology USA, Inc.
256 North Sam Houston Pkwy E. #115
HOUSTON TX 77060

Re: K100317

Trade/Device Name: System, X-Ray, Extraoral Source, Digital
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH, EHD, and MQB
Dated: February 3, 2010
Received: February 4, 2010

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of March 24, 2010.

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.

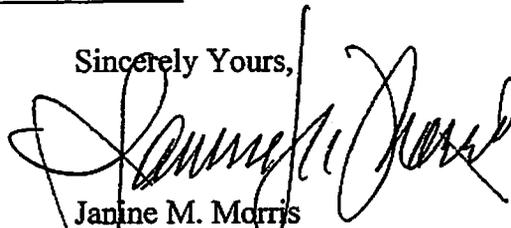
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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
Acting 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):

Device Name: PaX-Primo

Classification: System, X-Ray, Extraoral Source, Digital

Indications for Use:

PaX-Primo is a digital panoramic dental X-ray imaging system that uses a CMOS detector for a real time digital image acquisition. It is intended for producing diagnostic X-ray radiographic images of skull, dentition, and oral structures of the patient population targeting men, women and children. The device is operated and used by physicians, dentists and X-ray technologists.

Prescription Use
 (Part 21 CFR 801 Subpart D)

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

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

Concurrence of CDRH, Office of Device Evaluation(ODE)



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K108317

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