K102196

MAR 25 2011

510(k) Summary (Revised)

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

Date

November 22, 2010

Manufacturer

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Contact person: Mr. Dave Kim

Trade/Proprietary Name: PaX-Zenith3D

Common Name: Computed Tomography X-ray System

Classification Name:

System, X-ray, Tomography, Computed (21CFR 892.1750, Product code OAS, Class2)

Description:

PaX-Zenith3D is a dual X-ray machine which combines cone beam CT and panoramic X-ray modality to offer high definition digital diagnostic images in multi FOV for dental practitioners. Separately embedded panorama and CT sensors capture 2D and 3D images based on digital and CT technology while the most advanced digital imaging process enables the capture S/W program to provide one of the most effective image analysis and diagnosis in real time.

Indication for use:

PaX-Zenith3D is a computed tomography x-ray system intended to take panoramic, cross-sectional images of the oral and craniofacial anatomy and provide diagnostic information for children and adults clinical care in dentistry. The device is operated and used by x-ray technicians and dentists including oral surgeons.

Predicate Device:

Manufacturer : E-WOO Technology Co., Ltd.
Device : Picasso-Duo
510(k) Number : K090991 (Decision Date – 10/9/2009)

Substantial Equivalence:

PaX-Zenith3D described in this 510(k) has the similar intended use and technical characteristics as the Picasso-Duo of E-WOO Technology Co., Ltd.

The indications for use, material, form factor, performance, and safety characteristics between PaX-Zenith3D and the predicate device are similar. The primary differences are size, cosmetic, structure and component used only. Accordingly we can claim the substantially equivalence of PaX-Zenith3D to the predicate device.

The actual spatial resolution data for a digital panorama image for Xmaru1501CF for PaX-Zenith3D and S7199-01 for Picasso-Duo are almost identical after considering pixel binning of S7199-01, 5.0 lp/mm(Xmaru1501CF) and 5.2 lp/mm(S7199-01), respectively. Further technical details of the pixel binning for S7199-01 is described in the Executive Summary (Tab 10).

The similar technical characteristics of both devices are further described in the SSXI Non Clinical Report (Tap 25, 26, and 27) in terms of MTF, DQE, and SNR comparison. Finally, the sample clinical images for both devices have been included in the Clinical Report (Tab 28) to demonstrate the similar quality of images taken from both devices as well.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 (A1+A2, 1995), IEC 606061-1-1(2001), IEC 60601-1-3(Ed.1, 2006), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed.1, 1993), IEC 60601-2-32 (Ed.3, 2007) and IEC 60601-2-44 (Ed.2+A1, 2002) were 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" were performed.
All test results were satisfactory.

PaX-Zenith3D also meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

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-Zenith3D 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.
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Medical Device Regulatory Consultant
VATECH America
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MAR 25 2011

Re: K102196
Trade/Device Name: PaX-Zenith3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: March 8, 2010
Received: March 16, 2010

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,

Mary S. Pastel, Sc.D.
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-Zenith3D

Classification: Computed Tomography X-ray System

Indications for Use:

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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)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Mary S Patel

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

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