K090171

APR 30 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 892.1750.

Date: Dec. 01, 2008

1. Company and Correspondent making the submission:

Name: E-WOO Technology Co., Ltd.

Address: 1F, 4F, Yunmin Technotown, 473-4, Bora-Dong, Giheung-Gu, Yongin-Si, Gyeonggi-Do, 446-904, KOREA

Telephone : +82-31-285-6950

Fax : +82-31-286-3007

Contact : Mr. DongTaek, Oh

Internet : http://www.e-wootech.com

2. Device :

Trade/proprietary name	: PaX-Reve3D
Common Name	: Computed Tomography X-Ray System
Classification Name	: X-ray, tomography, computed, dental

3. Predicate Devices

Predicate Device A:

Manufacturer	: Vatech Co., Ltd.
Device	: PAX-500
510(k) Number	: K082350

Predicate Device B:

Manufacturer	: E-WOO Technology Co., Ltd.
Device	: EPX-Impla; Picasso-Trio
510(k) Number	: K070658

4. Classifications Names & Citations :

21CFR 892.1750, OAS, X-ray, tomography, computed, dental, Class2

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5. Description :

5.1 General

The PaX-REVE3D is a computed tomography x-ray system which is a diagnostic x-ray system intended to produce panoramic, cephalometric and cross-sectional images for dental examination and diagnosis of diseases of the teeth, jaw and oral structure by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. The device is operated and used by physicians, dentists, and x-ray technologists.

5.2 Product features

(1). Condition of Input

1-1. Rated input voltage : AC 110 / 220V ± 10%, Single-Phase

1-2. Guaranteed working voltage

1) 110V Mode : 100 ~120V

2) 220V Mode : 200 ~240V

1-3. Possible working voltage

1) 110V Mode : 90 ~130V

2) 220V Mode : 180 ~ 250V

1-4. Total Power : 2.0KVA

Output Power Max.: 90kV, 10mA, 30s

Nominal electric power: 40-90kV, 2-10mA, 8-30s

1-5. Rated input frequency : 50Hz / 60Hz

1-6. Insulation withstanding : below than 1.5KV cap for more than one minute between first test and second test.

1-7. Circuit Breaker: 13.5A

(2) Capture mode

1-1. Capture modes of Panoramic System

Panoramic for adults

Panoramic for children

Left side of dentition

Right side of dentition

Anterior part of dentition

TMJ (Mouth open and close) - TBD

Anterior view of asal(maxillary) sinuses - TBD

1-2. Capture modes of Cephalometric System

Lateral view

Posterior-Anterior view

Carpus view

1-3. Capture mode of Computed Tomography System

3D image

(3) X-ray Generator

1-1. Ripple : <4 (%)

1-2. converter frequency : 36 kHz push-pull

1-3. Tube type : D-051, stationary anode type

1-4. Nominal power : Below than 1.3 KW

1-5. Tube voltage : 40 – 90 kV (adjustable by 1 kV)

For Panoramic Unit (40 – 90kV)

For Cephalometric Unit (60 – 90kV)

For CT Unit (50 – 90kV)

Note: Protect > 50°C

1-6. Tube current : 1 – 10 mA (adjustable by 1mA)

For Panoramic Unit (2 – 10mA)

For Cephalometric Unit (2 – 10mA)

For CT Unit (2 – 10mA)

1-7. Guaranteed working voltage

1) 110V Mode : 100 ~120V

2) 220V Mode : 200 ~240V

1-8. Possible working voltage

1) 110V Mode : 90 ~130V

2) 220V Mode : 180 ~ 250V

1-9. Cooling : by force, one minute for cooling / protect ≥50°C

6. Indication for use :

The PaX-REVE3D is a computed tomography x-ray system which is a diagnostic x-ray

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system intended to produce panoramic, cephalometric and cross-sectional images for dental examination and diagnosis of diseases of the teeth, jaw and oral structure by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. The device is operated and used by physicians, dentists, and x-ray technologists.

7. Comparison with predicate device :

The subject device and predicate devices are substantially equivalent, having the same intended use, form factor, material, performance and safety characteristics. The differences are cosmetic, arrangement and components use only. The predicate device's 510K marketing clearance letters, 510K summaries and product information are found in TAB O, P Q, respectively.

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-1-3, EN/IEC 60601-2-7, EN/IEC 60601-2-28, EN/IEC 60601-2-32 and EN/IEC 60601-1-44 was performed, and EMC testing was conducted in accordance with a standard EN/IEC 60601-1-2. All test results were satisfactory.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, E-WOO Technology Co., Ltd. concludes that PaX-Reve3D is safe and effective and substantially equivalent to predicate devices as described herein.

10. E-Woo Technology Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2009

E-WOO Technology Co., Ltd.
% Mr. Vincent Lee
Regulatory Compliance Officer
E-WOO Technology USA, Inc.
256 North Sam Houston Pkwy E. #115
HOUSTON TX 77060

Re: K090171
Trade/Device Name: PaX-Reve3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: March 24, 2009
Received: March 30, 2009

Dear Mr. Lee:

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 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.

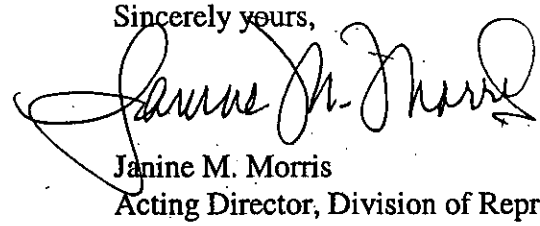
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090171

Device Name: PaX-Reve3D

Classification: X-Ray, Tomography, Computed, Dental

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 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 Reproductive, Abdominal and Radiological Devices
510(k) Number K090171