K090467

## 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: November 4, 2009

JAN - 8 2010

1. Company and Correspondent making the submission:

Name: Vatech Co., Ltd.
Address: 23-4, Seogu-Dong, Hwaseong-si, Gyeonggi-do, 445-170, Korea
Telephone: +82-31-377-9104
Fax: +82-31-337-1882
Contact: Mr. DongTaek, Oh
Internet: http://www.vatech.co.kr

2. Device :

| | |
|---|---|
| Trade/proprietary name | : PaX-Uni3D |
| Common Name | : Digital X-ray imaging system |
| Classification Name | : X-ray, tomography, computed, dental |

3. Predicate Device :

| | |
|---|---|
| Manufacturer | : Vatech Co., Ltd. |
| Device | : PaX-500 |
| 510(k) Number | : K082350 (Decision Date - Oct. 10. 2008) |

4. Classifications Names & Citations :

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

5. Description :

5.1 General

The PaX-Uni3D diagnostic equipment consists of Digital Computed Tomography, Panoramic, and Cephalometric dental X-ray system. This device is a system based on Digital X-ray Imaging System (Computed Tomography Sensor to Capture X-ray Digital Computed Tomogram Scanned Image)

5.2 Product features

1). Condition of Input

- Rated input voltage: AC 220V
- Guaranteed working voltage

  -110V Mode: 100 ~120V / 220V Mode: 200 ~240V
- Possible working voltage

  -110V Mode : 90 ~130V / 220V Mode : 180 ~ 250V
- Rated input frequency: 50Hz/60Hz
- Insulation withstanding: below than 1.5KV cap for more than one minute between first test and second test.

2) Capture mode

- Panoramic System

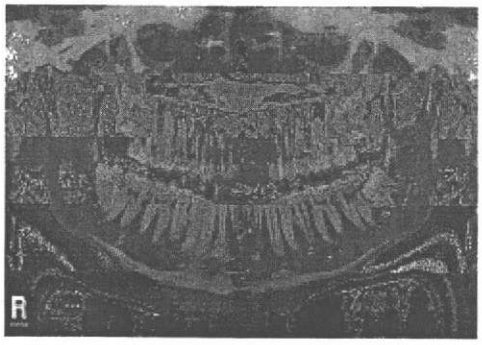
  2-1 Standard Mode

  - ✓ Standard Panoramic
  - ✓ Hemi-Panoramic (Left and Right)
  - ✓ Frontal Dentition
  - ✓ Sinus
  - ✓ TMJ open/Close mouth: 4 views

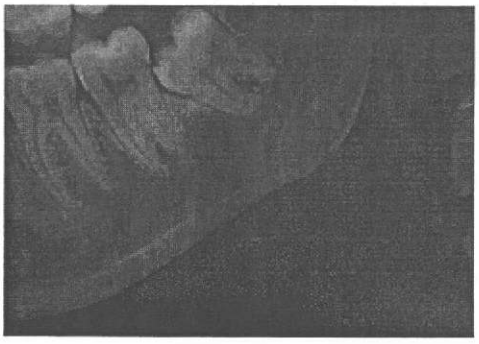
  2-2 Special Mode

  - ✓ Incisor clear
  - ✓ Orthogonal
  - ✓ Canal clear
  - ✓ Maxillary Molar clear

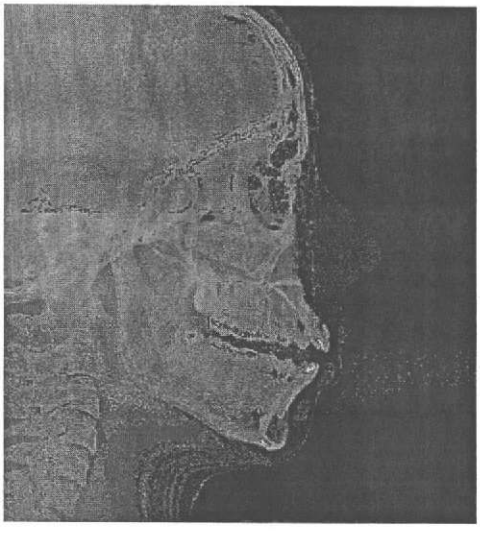
[Standard Panoramic]

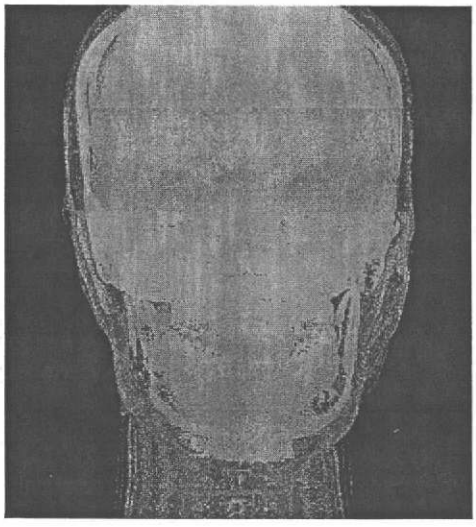



[Canal clear]



- Capture modes of Cephalometric System
  - ✓ Latero-Lateral [Lateral Mode]
  - ✓ Posterior – Anterior [PA Mode]
  - ✓ Carpus
  - ✓ SMV





- Tomography
  - ✓ Shooting Mode : Mandible/ Maxillary/ Occlusion/ TMJ
  - ✓ Shooting Range : All kind of tooth
  - ✓ Basic Display View : View Available

- ✓ Reference Panorama View : Available
- ✓ 3D Image
  - -Standard Viewer
  - -Professional Viewer

6. Indication for use :

The PaX-Uni3D 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.

7. Comparison with predicate device :

Vatech Co., Ltd., believes that the PaX-Uni3D is substantially equivalent to the PaX-500 of Vatech Co., Ltd.

8. 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, IEC 60601-2-32 and IEC 60601-2-44 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. All test results were satisfactory.

9. 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 The PaX-Uni3D is safe and effective and substantially equivalent to predicate devices as described herein.

10. Vatech 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN – 8 2010

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

Re: K090467
Trade/Device Name: PaX-Uni3D
Regulation Number: 21 CFR 872.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: November 4, 2009
Received: November 13, 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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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): K090467

Device Name: PaX-Uni3D

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 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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090467