K082350

OCT 10 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.18.

Date: July. 30, 2008

1. Company and Correspondent making the submission:

Name – Vatach Co., Ltd.

Address – 473-4, Bora-dong, Giheung-gu
Yongin-si, Kyunggido, KOREA, 446-904

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-500

Common Name : Digital dental panoramic and cephalostat with computed tomography x-ray system

Classification Name : X-RAY, TOMOGRAPHY, COMPUTED, DENTAL

3. Predicate Device :

Manufacturer : Instrumentarium Dental Inc.

Device : OP-200

510(k) Number : K063773 (Decision Date - Jan. 31. 2007)

4. Classifications Names & Citations :

21CFR 892.1750, OAS, X-RAY, TOMOGRAPHY, COMPUTED, DENTAL Device Class2

5. Description :

5.1 General

PaX-500 is an extraoral dental digital x-ray source generating diagnostic X-ray imaging from Digital Tomography, Panoramic, and Cephalometric dental X-ray modality. This Xray system device is based on digital X-ray imaging sensor to capture X-ray digital tomogram scanned Image 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.

5.2 Product features

1). Condition of Input

- Rated input voltage : AC 230V
- Guaranteed working voltage

  -110V Mode : 100 ~120V / 220V Mode : 210 ~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

- Capture modes of Cephalometric System : Option
  - ✓ Latero-Lateral [Lateral Mode]
  - ✓ Posterior – Anterio [PA Mode]
  - ✓ Carpus
  - ✓ SMV
- Tomography : Option
  - ✓ Shooting Mode : Mandible/ Maxillary/ Occlusion/ TMJ
  - ✓ Shooting Range : All kind of tooth
  - ✓ Basic Display View : View Available
  - ✓ Reference Panorama View : Available
  - ✓ Image : Standard viewer / Professional Viewer

6. Indication for use :

The PaX-500 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 tissue by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles.

7. Comparison with predicate device :

Vatech Value Co., Ltd., believes that the PaX-500 is substantially equivalent to the OP-200 of Instrumentarium Dental Inc.

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-2-7, EN/IEC 60601-2-28 and EN/IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2, EN/IEC 61000-3-2 and EN/IEC 61000-3-3. All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 892.1750 and based on the information provided in this premarket notification Vatech Co., Ltd. concludes that The PaX-500 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
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2008

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

Re: K082350
Trade/Device Name: PaX-500
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: September 25, 2008
Received: September 26, 2008

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the 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 894.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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
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): K082350

Device Name: PaX-500

Indications for Use:

The PaX-500 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 structures by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles.

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 K082350