510(K) SUMMARY
February 15, 2008
K073365

APR - 8 2008

SUBMITTER INFORMATION:

Vatech Co., Ltd.
75-11 Seogu-ri, Dongtan Myeon
Hwaseong-si, Gyeonggi-do
445-811 Korea

APPLICANT/FDA AGENT/CORRESPONDING OFFICIAL INFORMATION:

North American Technical Services (NATS) Corp
30 Northport Rd
Sound Beach, NY 11789
Tel: 631-744-0059 Fax: 631-744-0192 Email: natscorp@aol.com
Contact: Stephen T. Mlcoch

DEVICE NAME:

Name: Digital X-Ray Imaging System
Proprietary Model: PaX-P&P
Classification: System, Xray Extraoral Source Digital (code MUH)
Class 2 - 872.1800

PREDICATE DEVICES:

Sinora Dental Systems Digital Xray System Model Orthophos 3/3 Ceph/3DS – K990528
Intrumentarium Corp. Digital Xray System Model Orthoceph OC100D – K001439

DESCRIPTION:

Vatech Model PaX-P&P is a digital panoramic dental imaging system. It uses high resolution CCD detector for real time digital image acquisition. It has lower radiation dose results, simple user interface and high quality producing capability.

INTENDED USE:

The Vatech system is intended as an extraoral digital xray system that allows for panoramic tomographic imaging and teleradiography. It essentially has the same use as the predicate devices for X-ray computed tomography of the head and neck for dental, oral, and related medical use imaging.

COMPARISON TO PREDICATE DEVICES:

The Vatech system has the same use and capability as both of the predicate devices named. The Vatech and Instrumentarium high voltage tubes are from the same Toshiba tube family and have the same fundamental electronic design. The CCD, radiographic, extraoral sensing and imaging methods are all similar characteristics used by these systems. They all have rotating image capability and similar chin rest positioning.

Small differences in methodology, technique, and cosmetic appearance offer no new concerns regarding safety and effectiveness. The Vatech system is technologically equivalent in concept, function and performance to the predicate devices.

CONCLUSION:

The Vatech model PaX-P&P has been developed and validated according to all applicable standards. Evaluations have proven that the system is safe and effective for the intended use. Risk analysis and safety certifications reveal that there are no new safety issues associated with this system as compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2008

Vatech Co., Ltd.
c/o Mr. Stephen T. Mlcoch
North American Technical Services Corporation
30 Northport Road
SOUND BEACH NY 11789

Re: K073365
Trade/Device Name: Vatech Co., Ltd. Digital X-ray Imaging System
Model PaX-P&P
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory class: II
Product Code: MUH
Dated: February 18, 2008
Received: March 5, 2008

Dear Mr. Mlcoch:

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 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

Nancy C Brogdon

Nancy C. Brogdon
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):

Device Name: Vatech Co., Ltd. Digital X-ray Imaging System Model PaX-P&P

Incications for Use: 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 user interface, and produces high quality images. 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.

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073365