



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Paxeramed Corporation
% Mr. Carl Alletto
Consultant
Otech, Inc.
2001 E. Oak Shores Drive
AUBREY TX 76227

October 31, 2013

Re: K132586
Trade/Device Name: PaxeraPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 8, 2013
Received: September 5, 2013

Dear Mr. Alletto:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

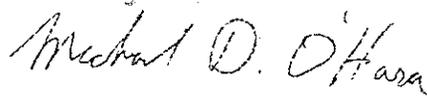
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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>. 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,

A handwritten signature in cursive script that reads "Michael D. O'Hara".

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132586

Device Name: Paxera PACS

Indications for Use:

The *Paxera PACS* is a scalable medical image and informatics system intended to receive, transmit, display, print and process digital images from medical image modality supporting the DICOM 3.0 standard, these modalities are Magnetic Resonance (MR), Computed Tomography (CT) Computed Radiography (CR), Digital X-Ray (DR), Digital Mammography (MG), X-Ray Angiography (XA), Ultrasound (US), Nuclear Medicine (NM), and Positron Emission Tomography (PT).

The *Paxera PACS* workstation provides the user with the ability to display, manipulate, attach diagnostic reports, archive, transmit and print images using DICOM and other computer industry standard interfaces and standards.

Mammography images intended for primary interpretation must be acquired for an FDA approved Full Field Digital Mammography (FDDM) device. In addition, the FDDM device must be able to provide to the *Paxera PACS* "for presentation" a viewable DICOM image as approved by FDA for primary interpretation. If images are sent to a film printer such printers must be FDA approved for diagnosis of digital mammography images. If digital mammography images are viewed on a display that display must be cleared by the FDA for primary diagnosis of digital mammography images.

The *Paxera PACS* allows for integration with many open interfaces including DICOM, Web Client, and Archiving devices. The *Paxera PACS* server infrastructure software facilitate database management and image management, printing, HL-7 interfacing and all DICOM services such as Store/Retrieve, Query and Send.

The *Paxera PACS* is intended for use by trained medical professionals including but not limited to, Radiologists, Physicians and Medical Technologists. It is the user's responsibility to ensure quality by taking measures to achieve the proper lighting conditions and image compression ratios consistent with the clinical requirements of the intended use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)

Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k) K132586