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## A. 510(k) Summary

DEC 2 0 2011

1. Name and Address of Manufacturer

   John. J Craig, Vice President/Manager
   EponaTech LLC
   6720 Linne Road
   Paso Robles, CA 93446
   (805) 239-3505

2. Establishment registration number

   K103554

3. Name, title and phone number of contact

   K. Brian Matlock
   Attorney for Applicant
   Matlock Law Group, PC
   1485 Treat Blvd, Suite 200
   Walnut Creek, CA 94597
   Phone: (925) 944-7131

4. Date Prepared

   December 5, 2011

5. Device Tradename

   Metron-MD

6. Device Common Name

   Picture archiving and communications system (PACS)

7. Product Code:

   LLZ

8. Regulation No.

   21 CFR 892.2050

9. Device Classification

   Class II, Image Processing System

10. Predicate Devices

The Metron-MD imaging software application is substantially equivalent to the following devices.

| Manufacturer | Product Name | 510(k) No. |
|---|---|---|
| Oehm and Rehbein | dicomPACS | K070618 |
| Viztek, Inc. | Onyx-RAD Telemedicine PACS | K003607 |

11. Device Description

Metron-MD is a clinical software program that allows medical professionals to acquire, display, manipulate and archiving medical images. It offers features (e.g. annotation, zoom, calibration, mark-up, measurement, etc.) routinely used by medical professionals, such as radiologists and orthopedists. Metron-MD supports the DICOM standard and accepts file formats including JPEG, Bitmap, TIFF, avi, and DICOM. Metron-MD runs on Windows based PC-compatible computers, accepts existing image files, and captures images and videos from capture devices such as USB video cameras, CR and DR systems, Digital Camera Media, and TWAIN images sources, etc.

12. Intended Use

Metron-MD is a clinical software program that is intended to acquire, display, annotate, calibrate, mark-up, analyze, store, print, and distribute medical images using standard PC-compatible computers. Images can be acquired from image files and various image capture devices (e.g. computed radiography devices, digital radiography devices, digital video capture devices, and other imaging devices such as scanners). Metron-MD supports adding notes and other mark-up to images. Using Metron-MD, medical professionals can start with raw images, and quickly and easily produce formatted multi-page reports stored and organized in a searchable database. Metron-MD is not intended to provide medical diagnosis or a recommended treatment approach.

13. Technological Characteristics

Metron-MD is a stand-alone software program that runs on Windows based operating system (Windows XP and 7) on any hardware platform meeting the minimum system requirements.

Metron-MD allows digital image processing and measurement capability. The program can transmit images to remote viewing stations over a medical imaging network.

Metron-MD does not contact the patient, nor does it control any life-sustaining devices. Medical professionals with adequate expert knowledge and ample opportunity for competent human intervention interpret displayed and/or printed images and information.

14. Testing

Metron-MD is tested according to the specifications documented in this notification. Metron-MD is demonstrated to perform as intended.

15. Conclusions

Metron-MD is a medical device that is substantially equivalent to similar features in the Predicate Devices and has the same intended uses and technological characteristics. The different features included in the Metron-MD software do not affect the safety or effectiveness of the device.

This premarket notification contains sufficient information to establish substantial equivalence to the Predicate Devices.

16. Applicable Mandatory and Voluntary Standards

a. Radiation Control for Health and Safety Act

Not applicable.

b. CDRH – Recognized Voluntary Standards

i. DICOM

(1) Metron-MD supports and conforms to the DICOM standard. See **Exhibit 1** for "EponaTech Metron-MD DICOM Conformance Statement."

(2) Declaration of Conformance

Pursuant to Form FDA 3514 (3/08) and in my capacity as *Vice President/Manager* of ***EponaTech LLC***, I certify that to the best of my knowledge I believe that Metron-MD conforms with DICOM standard Version 3.0.

ii. JPEG

Metron-MD supports the JPEG (Joint Photographic Experts Group) standard, which specifies methods for the compression (reversible and irreversible) of digital medical images.

John Craig, Vice President

20 DEC. 2011
(Date)

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

Epona Tech LLC
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Principal
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DEC 2 0 2011

Re: K103554
Trade/Device Name: Epona Tech Metron-CP/MD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 14, 2011
Received: December 15, 2011

Dear Mr. Matlock:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Indications for Use Statement

The EponaTech Metron-CP/MD is a clinical imaging software application for use with DR and CR radiography systems, primarily focused on chiropractic and podiatry use. Metron-CP/MD processes images using state of the art wavelet filtering techniques from various imaging sources and then makes them available to display, edit, review, store, print and distribute using standard PC hardware. Metron-CP/MD stores and organizes the images (radiographs, ultrasounds, photographs, etc), and provides many value added features for review and analysis by trained medical practitioners. Advance imaging algorithms produce the best image possible from the imaging hardware. The filters are customizable by the user and organized in Metron-CP/MD's searchable database for later review. Metron-CP/MD also supports adding notes, taking accurate physical measurements, and producing other mark-ups to images to aid in analysis over time. Metron-CP/MD also allows the easy creation and editing of formatted, multi-page reports.

Metron-CP/MD is currently intended for chiropractic, podiatry use, and general human radiography. *It is not intended for mammography use.*

Metron-CP/MD's features advance imaging algorithms, calibration and measurement tools, multi-imaging stitching, report generation, and full compliance with voluntary Digital Imaging and Communications in Medicine (DICOM) standards. The filters are customizable by the user and organized in Metron-CP/MD's searchable database for later review. Users then have the ability to put together multi-page formatted reports that can be used in connection with other medical professionals, or provided as reference to patients. (See 21 CFR 892.2050)

*In accordance with 21 CFR 801 Subpart D, the software is intended for prescription use.*

Prescription Use: ___X___ (21 CFR 801 Subpart D)  And/Or  Over-The-Counter Use: _____ (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103554