MAR 9 2006

510(k) Premarket Notification Summary of Safety and Effectiveness Information	MDxNet

Section 5.0: 510K SUMMARY

5.1 Contact Information

Establishment:	CyberMDx, Inc. Richmond Square, Suite 166W Providence, RI 02906
Official Correspondent:	John Coleman, PhD Chief Technology Officer (CTO) CyberMDx, Inc Richmond Square, Suite 166W Providence, RI 02906 Phone: (401) 274-5633 FAX: (401) 633-6544
Prepared By:	Bonne Farberow, RN, CCRA, CCRP Regulatory Affairs Consultant 53 Meetinghouse Ct Shamong, NJ 08088
Date Summary Prepared:	December 24, 2005

Section 5.2 Name of Device

Proprietary:	MDxNet
Common/Usual Name:	Image Processing Server
Classification:	System, Image Processing, Radiological Class II
Product Code:	90-LLZ

Section 5.3 Substantially Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for the predicate devices. In addition, bench testing was conducted to establish MDxNet's accuracy, performance to specification, as well as testing to accepted industry standards under Investigational Review Board (IRB) approval and in the laboratory setting. The predicate devices are as follows

- AquariusNet Server, Teracon, Inc., K012086
- TeraRecon IiVS, TeraRecon, Inc., K994329
- Imatron Ultra Access, AccuImage, 972903
- EchoTech 3D Imaging Systems, K013088
-

These devices are substantially equivalent in terms of basic design, features and intended use, though MDxPAC and MDxServer have the additional capability pending end user needs and requirements of integration of FDA approved devices such as the IQmark Spirometry and ECG.

Table 5-1 compares MDxNet with features of its Predicate Devices.

Table 5-1: Predicate Devices

Feature	MDxNet Submission - Pending	Aquarius Net Server K012086	Imatron Ultra Access 972903	TeraRecon IiVS K994329	EchoTech 3D Imaging Systems K013088
2 D Image Review	Yes	Yes	Yes	Yes	Yes
Multiplanar reformatting	Yes	Yes	Yes	Yes	Yes
3D Volume Rendering	Yes	Yes	Yes	Yes	Yes
Maximum Intensity Projection	Yes	Yes	Yes	Yes	Yes
Image Archiving	Yes	Yes	Yes	Yes	Yes
Image Filming	Yes	Yes	Yes	Yes	Yes
Lossy Image Compression	No	Yes	Yes	Yes	
Image Transfer or Network Connectivity	Yes	Yes	Yes	Yes	Yes
Examination of 2D image as a 3D volume	Yes	Yes	Yes	Yes	Yes
CT and Calcium Scan	No	Yes	Yes	Yes	No
Comparison of Multiple Scans or Side by Side Comparison	Yes	Yes	Yes	Yes	Yes
Indications of use – general medical imaging units or sites; acquisition, analysis, store and retrieve digital ultrasound	Yes	Yes	Yes	Yes	Yes
Computer Platform	Yes	Yes	Yes	Yes	Yes
Image Display	Yes	Yes	Yes	Yes	Yes
Operating System	Yes	Yes	Yes	Yes	Yes
*Capture and store ECG	Yes	No	No	No	No
Indication (s); Assess heart wall and/or function for abnormalities	Yes	No	No	No	No
*Capture and store Spirometry (VC, etc.)	Yes	No	No	No	No
Indication (s); Assess Pulmonary function	Yes	No	No	No	No

*Utilizing FDA approved devices; Terason K992505, IQmark ECG (Registration #2081230) and IQmark Spirometer K002499

Note - Tempus 2000; K010436 (for integration of COTs)

5.4 Device Description and Function

MDxNet consists of MDxPAC, MDxStation (PC or Notebook, laptop computer), MDxServer, and the proprietary software component called MDxView. MDxPAC consists of limited hardware, that bundle and power FDA approved Commercial Off-The-Shelf devices (COTS). MDxNet features an integrated 2D/3D streaming engine which permits PC's or notebooks to control the server and to review 2D and 3D reconstructions. MDxNet is capable of image review, archiving, data collection, database maintenance, reporting and basic 3D capabilities including color rendering. Upon receipt of FDA approval to market MDxNet, finished devices will be distributed only under direction and/or orders of physicians.

MDxNet inherits and integrates concepts first pioneered in the National Aeronautics and Space Administration (NASA) sponsored Telemedicine Instrument Pack (TIP) project and the Defense Advanced Research Projects Agency (DARPA) sponsored Medical Ultrasound Three-dimensional, Portable with Advanced Communication (MUSTPAC) project, and its predecessors. It expands capability to include a server component, augments data acquisition to include wireless options, redesigns the Graphical User Interface (GUI) for more intuitive interaction and provides improved packaging for better usability.

MDxNet has the capability to record ultrasound transducer spatial position in six degrees of freedom during use. Coordinate tracking is achieved with a miniature magnetic field sensor within a transmitted pulsed magnetic field. This is done by attaching a plastic holding plate to the FDA approved probe of the host Ultrasound system, to which the receiver of an electromagnetic sensor device is attached.

2D ultrasound images are acquired sequentially in a series of steps as the ultrasound transducer is moved across the patient scan site. The resulting set of digitized 2D images is then converted into a 3D data volume.

IQmark Digital ECG and Spirometer both FDA approved devices have been integrated into MDxNet as requested by the end user of the validation study. The Midmark software for each of these devices and indications of use have not been altered, though permit the end user as demonstrated in both clinical studies to capture additional potentially key clinical results within MDxNet for data collection, review, comparison, reporting and archiving.

Hardware & Software Information:
The MDxNet utilizes standard "off the shelf" personal computer systems and Bluetooth wireless as its hardware platform. The MDxPAC component includes a Class B magnetic tracking as well as it's own power supply including rechargeable batteries. The software requires the minimum use of Windows XP operating system and a Pentium III – class processor or its equivalent. All hardware testing will be conducted and meet the specified acceptance criteria before the device is marketed.

The level of concern relative to the software has been determined as minor using the decision tree provided in the revised FDA Software Guidance, May 11, 2005.

5.5 Indications/Intended Use:
MDxNet is intended for use under physician's orders and/or oversite and management. MDxNet is indicated for acquisition of related sets of 2D ultrasound images, 3D reconstruction of ultrasound images. MDxNet system is indicated to acquire, digitize, archive and retrieve single and sequences of 2D ultrasound images.

The assessment of pulmonary function in male/female patients through Spirometry and to provide 12-lead resting electrocardiogram (ECG) utilizing FDA approved devices which permits the detection of abnormalities in the transmission of the cardiac impulse through the heart muscle and serves as an important aid in the diagnosis of heart ailments.

Contraindications:
MDxNet is not intended for long term monitoring. MDxNet is not intended to be used in strong magnetic or electromagnetic fields which are generated for medical purposes, i.e. Magnetic Resonance Imaging (MRI).

Disposable pneumotach mouthpieces are clean though are not sterile and should not be placed over open wounds that are prone to infection. There are no other known medical contraindications other than the physical limitations of the patient.

5.6 Technological Comparison with Predicate Devices
Two MDxNet Systems were developed to acquire potential end user input and to allow validation of the software, hardware, server and integration under Investigational Review Board (IRB) approval in a medical clinic setting.

Clinical testing was conducted according to an IRB approved protocol. Continual nonclinical testing is being conducted through internal company procedures according the FDA 21CFR820 Quality System and Current Good Manufacturing Practices. Additional nonclinical testing will be conducted by a third party laboratory. Test results to date included elsewhere support the conclusion that the actual device, software and hardware satisfies the design intent. Actual device performance as tested internally and by third parties (including controlled clinical trials) conforms to the system performance standards and has met expectations."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

John Coleman, Ph.D.
Chief Technology Officer
cyberMDx, Inc.
1 Richmond Square, Suite 166W
PROVIDENCE RI 02906

Re: K060035
Trade/Device Name: MDxNet
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 28, 2005
Received: January 5, 2006

Dear Dr. Coleman:

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 (Premarket Approval), 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.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" (21 CFR 807.97). 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) 443-6597 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

Section 4.0: Indications for Use
510(k) Number (if known): K060035
Device Name: MDxNet
Indications for Use:
MDxNet is intended for use under physician's orders and/or oversight and management.

MDxNet is indicated for acquisition of related sets of 2D ultrasound images and 3D reconstruction of ultrasound images in the adult and pediatric patient utilizing existing ultrasound systems. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 2D and 3D image processing. MDxNet is indicated to acquire, digitize, archive and retrieve single or sequences of 2D ultrasound images.

MDxNet is intended as a general purpose digital image processing and archiving tool for use in abdominal, pelvic, fetal, cardiac, peripheral vascular and neurovascular imaging.

MDxNet add-on indications are for the assessment of pulmonary function to acquire, analyze, store and retrieve this assessment in male/female adult and pediatric patients utilizing FDA approved Spirometry. MDxNet additional add-on will provide 12-lead resting electrocardiogram (ECG) which permits the detection of abnormalities in the transmission of the cardiac impulse through the heart muscle and serves as an important aid in the diagnosis of heart ailments through utilizing 12-lead ECG.

MDxNet intended use is for medical clinics, including though not limited to infirmary, hospital, military, remote and urban clinics.

Contraindications:
MDxNet is not intended to be used in strong magnetic or electromagnetic fields which are generated for medical purposes, i.e. Magnetic Resonance Imaging (MRI).

MDxNet is not intended for long term monitoring. This device is not intended to nor does it sound alarms for any physiological parameters. The ECG is not intended to be utilized on patients with prosthetic limbs.

Disposable pneumotach mouthpieces are clean though are not sterile, and should not be placed over open wounds that are prone to infection. There are no other known medical contraindications other than the physical limitations of the patient.

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060035