K043134

Metrx Workstation
Summary of Safety and Effectiveness

Submitter Name:	Medical Metrx Solutions, Inc
Submitter Address:	12 Commerce Avenue West Lebanon, NH 03784
Contact Person:	William F. Greenrose Senior Vice President
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Date Prepared:	November 9, 2004
Device Trade Name:	Metrx Workstation
Classification Name, Number & Product Code:	System, Image Processing, Radiological 21 CFR 892.2050 LLZ
Predicate Devices:	Preview® Treatment Planning Software; Medical Metrx Solutions, Inc. Vitrea 2; Vital Images, Inc.
Device Description and Statement of Intended Use	The Metrx Workstation is a software product that is intended for users to segment and differentiate tissues and anatomical structures from two-dimensional imaging data, and to construct accurate, three-dimensional models from these segmented data. Metrx also provides the user with tools to better visualize and analyze the processed data. Metrx data may be outputted as the source data for Preview® Treatment Planning Software. The Metrx Workstation product is not intended to provide medical diagnosis or a recommended treatment approach.
Summary of Technological Characteristics	A table comparing the Metrx Workstation to the predicate devices is attached. This comparison demonstrates the substantial equivalence of the Metrx Workstation to the predicate devices.

Feature	METRX Workstation	Preview® Treatment Planning Software	Vitrea™2 Version 3.4 Medical Image Processing Software
510(k) Number		K040852	K032748
Manufacturer	Medical Metrx Solutions, Inc.	Medical Metrx Solutions, Inc. (formerly Medical Media Systems, Inc.)	Vital Images, Inc.
Classification # & Product Code	21 CFR 892.2050 LLZ	21 CFR 892.2050 LLZ	21 CFR 892.2050 LLZ
Indications for Use	The Metrx Workstation is intended for users to segment and differentiate tissues and anatomical structures from two-dimensional imaging data, and to construct accurate, three-dimensional models from these segmented data. Metrx also provides the user with tools to better visualize and analyze the processed data. Metrx data may be outputted as the source data for Preview® Treatment Planning Software. The Metrx product is not intended to provide medical diagnosis or a recommended treatment approach.	The Preview® Treatment Planning Software is intended to provide accurate, alternative two-dimensional images, as well as three-dimensional models, of patient specific anatomy from existing two-dimensional scan data of organs and tissues.. The Preview® product offers the physician the capability to view existing scan data in a format that is more user friendly, and thus enhances the physician's capability to plan treatment. The Preview® product is not intended to provide medical diagnosis or a recommended treatment approach.	Vitrea™ 2 is a medical diagnostic workstation that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. In addition, Vitrea™2 has the following specific indications: VScore™ (K990442); Automated Vascular Measurement (K002519; Tumor Volume Measurement (K002519; CT Brain Perfusion (K003639); ImageCheckerCT
Product Components	Software	Software	Software & computer system
Read data in DICOM format	Yes	Yes	Yes
Imaging	2D and 3D	2D and 3D	2D and 3D
Operating platform	Modeling done by user on UNIX. Viewing software run on DOS/ Windows	Modeling done at MMS on UNIX.	Windows XP
Source of image data	Retrieval over network via DICOM or via hard media	Retrieval over network via DICOM or via hard media	Retrieval over network via DICOM
Viewing format	Multiple interactive 2D & 3D views	Multiple interactive 2D & 3D views	Multiple interactive 2D & 3D views
Analysis	Measurements performed on image on workstation	Measurements performed on image on workstation	Measurements performed on image on workstation
End user data manipulation	Data modeling performed by end user	Data modeling performed at MMS	Data manipulations performed by end user
Model manipulation	In multiple planes and orientation	In multiple planes and orientation	In multiple planes and orientation

2D = 2-Dimensional; 3D = 3-Dimensional

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2004

Medical Metrx Solutions, Inc.
% Ms. Patsy J. Trisler
Regulatory Consultant
5610 Wisconsin Avenue, #304
CHEVY CHASE MD 20815

Re: K043134
Trade/Device Name: Metrx Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 10, 2004
Received: November 12, 2004

Dear Ms. Trisler:

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/dsma/dsmamain.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 5.0

Indications for Use Statement

510(k) Number (if known): K043134

Device Name: Metrx Workstation

Indications for Use:

The Metrx Workstation is intended for users to segment and differentiate tissues and anatomical structures from two-dimensional imaging data, and to construct accurate, three-dimensional models from these segmented data. Metrx also provides the user with tools to better visualize and analyze the processed data. Metrx data may be outputted as the source data for Preview® Treatment Planning Software.

The Metrx product is not intended to provide medical diagnosis or a recommended treatment approach.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use	

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043134

(Optional Format 1-2-96)