K062229

1. 510K Summary:

SEP 11 2006

Submitted by: Medical Diagnostic Technologies, Inc.
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Suite 700
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Contact Person: James M. Benson
President & CEO
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Product Name: CTC Workstation

Common Name: Medical Image enhancement/processing system

Classification: LLZ; Class II; CFR 21 892.2050

Predicate Devices:

K # & Device Name	Manufacturer
K024028/K993802 SharpView/GOPView	ContextVision AB
K023772 KinetDx	Siemens
K052411 HIPAX	Steinhart Medizinsysteme

Description of Device:
Under the direction of the physician the device stores, displays, and enhances ultrasound images. The image enhancement is performed by assigning pixels numeric values. The system is comprised of a software package running on off-the-shelf hardware.

Intended Use:
The CTC Workstation system is intended for use by a qualified physician to direct the storage, display, enhancement, and viewing of ultrasound images.

Comparison with Predicate Devices:
CTC Workstation system's technology and indication for use was the determining factor in selecting predicate devices for substantial equivalence. All of the devices selected as predicates share the same core functions as CTC Workstation: storage, display, viewing, enhancement/quantification of ultrasound images. All of the devices receive images via a computer. All three devices offer image enhancement/quantification on a user directed basis. All three devices require a qualified physician to direct the device.

Performance Studies:
The CTC Workstation has completed design verification and validation tests for conformance with specifications.

Summary of Safety and Effectiveness Data:
CTC Workstation provides functionality that is substantially equivalent to the cited predicate devices. The potential hazards have been studied and controlled as part of the design and development control processes, including risk analysis, test and design considerations, and planned verification and validation testing processes. CTC Workstation does not include any new indications for use, nor does the use of this device raise any new potential hazards or safety concerns. Like the named predicates, CTC Workstation provides qualified personnel the ability to direct the storage, retrieval, enhancement, and viewing of ultrasound images. All of the devices are completely user controlled and ensures a minimal impact on the standard of care.

As can be seen from the comparison tables, the subject device has the same basic technology provided by the predicates. It is primarily a software device that performs post-processing of images for the purposes of storage, retrieval, enhancement, and viewing of ultrasound images to yield information which supports a trained physician. The main technological difference is that the MDT device uses a different set of known algorithms to perform enhancement and assign numeric values to pixels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 11 2006

Mr. James Benson
President and CEO
Medical Diagnostic Technologies, Inc.
8960 W. Tropicana Ave,Suite 700
LAS VEGAS NV 89147

Re: K062229
Trade/Device Name: CTC Workstation Model 2200
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 1, 2006
Received: August 2, 2006

Dear Mr. Benson:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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): K062229

Device Name: CTC Workstation Model 2200

Indications For Use: The CTC Workstation system is intended for use by a qualified physician to direct the storage, display, enhancement, and viewing of ultrasound images.

Prescription Use ✓ 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)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062229