B. ADMINISTRATIVE INFORMATION

JUL 1 4 2005

1. 510(k) Summary of safety and effectiveness

Manufacturer:

Address: Medstrat, Inc.
1901 Butterfield Road
Suite 600
Downers Grove, IL 60515
Phone: 630-960-8700
Fax: 630-960-9787

Contact Person: Robert J. Bishop

Summary Date: April 25, 2005

Device Name:

Trade name: echoeSYSTEM™
Common name: Medstrat ECHOES™ PACS
Classification name: Picture archiving and communication system

Predicate Device:

eFILM Workstation with Modules, K020995, eFilm Medical Inc.

Amicas Web/Intranet Image Server, K970064, Autocyt Group, Inc.

Device Description:

ECHOES™ is a client-server software system designed to allow viewing access to medical images on a personal computer by authorized medical professionals. This product is designed to function with off-the-shelf hardware and software products including standard communications products. It does not require specialized, or non-standard, devices of any type.

Image acquisition is via the industry standard DICOM 3.0 protocol allowing the images to be produced from the digital data originated by the imaging modality.

The software will run on standard off-the-shelf hardware and system configurations.

Intended Use:

The Medstrat echoeSYSTEM™ is intended to enable the communication, storage, viewing and manipulation of diagnostic medical images and data. The echoeSYSTEM™ can show images on workstations locally and/or across computer networks at widely

distributed locations. The echoeSYSTEM™ software is intended for assisting healthcare professionals in preoperative planning and postoperative evaluation of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and positioning the templates. The typical echoeSYSTEM™ users are trained professionals such as orthopedic surgeons, referring and collaborating physicians, and other authorized medical professionals.

It is the user's responsibility to bear in mind the display monitor's quality, ambient light conditions and the tradeoff between image compression ratio and clinical effectiveness for specific image study indications.

Substantial equivalence:

Feature	Efilm Workstation with Modules	Amicas Web/Intranet Server	EchoeSYSTEM
Indications for Use	Similar	Similar	Similar
Target Population	Health Professionals	Health Professionals	Health Professionals
Uses Off-the-Shelf Monitors	yes	yes	yes
Lossy Image Compression	yes	yes	yes
TCP/IP Communications	yes	yes	yes
Software Only	yes	yes	yes
Image Measurements	yes	yes	yes
DICOM image data	yes	yes	yes
Pixel-for-Pixel Zoom	yes	yes	yes
User Login/Authentication	NA	yes	yes
Digital templates	yes	no	yes
Editable state saves	no	no	yes

ECHOES™ has **Indications for Use** similar to other medical image devices such as to eFILM Workstation with Modules [K020995], eFilm Medical Inc. 510(k) Holder and Amicas Web/Intranet Image Server [K970064], Autocyt Group, Inc. 510(k) Holder. ECHOES™ also shares with these devices a **Target Population** that is competent health professionals. Also equivalent to these devices, the ECHOES™ design will operate with off-the-shelf hardware and systems.

Like the Amicas Web/Intranet Image Server [K970064], Autocyt Group, Inc. 510(k) Holder, ECHOES™ employs **Image Compression** to remove redundant or unimportant information in the original image data. The compression methods are believed to conform to the voluntary recognized consensus JPEG standard as declared in Section A.8 herein.

Like the eFILM Workstation with Modules [K020995], eFilm Medical Inc. 510(k) Holder, ECHOES™ provides image viewing and manipulation in a diagnostic setting affording users access to various image processing and **measurement** tools to assist them in viewing images. Users can overlay **templates** on medical images to aid in operative and non-operative treatment planning.

ECHOES™ provides secure Internet and extranet interfaces through **authentication** mechanisms, web accessible authentication servers and access for authorized users through secure protocols to web image servers. ECHOES™ provides functions for communicating, storing and editing **state save** data of annotations, measurements and image manipulation states intended to be used for supporting collaboration, clinical data collection and education among health professionals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 4 2005

Medstrat, Inc.
% Ms. Silvia Ankova
Project Manager
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
NORTHBROOK IL 60062

Re: K051745
Trade/Device Name: echoeSYSTEM™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 21, 2005
Received: June 29, 2005

Dear Ms. Ankova:

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

2. FDA Indication for Use Form

Indications for Use

510(k) Number (if known): K051745

Device Name: echoeSYSTEM™

Indications for Use:	The Medstrat echoeSYSTEM™ is intended to enable the communication, storage, viewing and manipulation of diagnostic medical images and data. The echoeSYSTEM™ can show images on workstations locally and/or across computer networks at widely distributed locations. The echoeSYSTEM™ software is intended for assisting healthcare professionals in preoperative planning and postoperative evaluation of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and positioning the templates. The typical echoeSYSTEM™ users are trained professionals such as orthopedic surgeons, referring and collaborating physicians, and other authorized medical professionals. It is the user's responsibility to bear in mind the display monitor's quality, ambient light conditions and the tradeoff between image compression ratio and clinical effectiveness for specific image study indications.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051745