K06 3392

DEC 1 2 2006

The Image Management Company

510(k) Summary

In accordance with the provisions of the Safe Medical Device Act of 1990, IMCO Technologies is providing a summary of safety and effectiveness information regarding the IMCO-STAT™ software

1.1 Company Identification

IMCO Technologies
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Pewaukee WI 53072
Contact: Mark Schwartz, President and CEO
Telephone: 262-523-4445
Fax: 262-523-1141
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1.2 Official Correspondent

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1.3 Date of Submission

November 7, 2006

1.4 Device Name

Classification Name:	System, Image Processing, Radiological
Common/Usual Name:	Soft-copy reading system
Proprietary Name:	IMCO-STAT™

1.5 Substantial Equivalence

The IMCO-STAT™ system has the same intended uses and technical characteristics as the Medical Insight EasyViz system (K051809) and Marotech, Inc . Marosis PACS System (K012844).

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Product Name	IMCO Stat	Medical Insight EasyViz	Marosis PACS
Graphical UI	Yes	Yes	Yes
Windows O.S. - Client	Yes	Yes	Yes
Uses Standard Monitor	Yes	Yes	Yes
Scales Image to Display	Yes	Yes	Yes
Image Input	DICOM 3.0	DICOM 3.0	DICOM 3.0
Images stored on remote Window server	Yes	Yes	Yes
Network Protocol	TCP-IP	TCP-IP	TCP-IP
Compression	JPEG 2K	Proprietary	JPEG 2K
Wireless Capability	Yes	Yes	No
Support Tablet PC, PDA, etc	Yes	Yes	No
Annotation	Yes	Yes	Yes
Image Measurement	Yes	Yes	Yes
Cine tool	Yes	Yes	Yes
Comparison Mode	Yes	Yes	Yes
Review Report from RIS	No	Yes	Yes
Designed for Use Inside and Outside Radiology	Yes	Yes	Yes
Flip / Rotate of Images	Yes	Yes	Yes
User Log In	Yes	Yes	Yes
Multiple Layout Options	Yes	Yes	Yes
WWL control & Pre-sets	Yes	Yes	Yes
Patient & Study Browser	Yes	Yes	Yes
Print to Paper Capability	No	Yes	Yes

1.6 Device Description and Intended Use

IMCO-STAT™ is a software device that receives digital images and data from existing imaging equipment using DICOM 3.0 communication protocols. Images and data are stored on the IMCO-STAT™ server in DICOM 3.0 Part 10 and JPEG format.

IMCO-STAT™ is designed to send reports, images, audio and video data to other workstations, Personal Digital Assistants (PDA) or Tablet PCs in wired or wireless environments. This is accomplished using an executable client application on a receiving entity with the appropriate hardware.

The images may be embedded for reference in a DICOM image comprised report data, for distribution across a network and storage in a Picture Archive Communication System (PACS) with the original exam series data. Wavelet files can also be created and stored utilizing the same process. The algorithms used to create JPEG and wavelet images follow known and accepted protocols.

IMCO-STAT™ uses standard off-the-shelf hardware and commercially available computer platforms and operating systems. The software communicates using the standard TCP/IP stack. The network used to support the TCP/IP stack is superfluous to IMCO-STAT™

1.7 General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use. The optional hardware components specified are off-the-shelf computer components

Validation and Effectiveness:

Testing of the software and related hardware has been performed by programmers, non-programmers, quality control individuals and potential customers.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Substantial Equivalence

As stated previously, IMCO-STAT™ is substantially equivalent to EasyViz software package and Marosis PACS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Mark L. Schwartz
President / CEO
IMCO Technologies
N27W23957 Paul Road #101
PEWAUKEE WI 53072

DEC 1 2 2006

Re: K063392
Trade/Device Name: IMCO-STAT™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 7, 2006
Received: November 9, 2006

Dear Mr. Schwartz:

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

IMCO™ TECHNOLOGIES

The Image Management Company

INDICATIONS FOR USE

510(k) Number (if known): K063392

Device Name: IMCO-STAT™

Sponsor Name: IMCO Technologies

Indications for Use:

IMCO-STAT™ is a software device that receives digital images and data from existing imaging equipment using DICOM 3.0 communication protocols. Images and data are stored on the IMCO-STAT™ server in DICOM 3.0 Part 10 and JPEG format.

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Prescription Use ☒ (21 CFR 801 Subpart D) And/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation

David Krug

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063392

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