MITSMED Medical Instrument Technology Co., Ltd.
4F-6, No. 99, Sec 1, NanKan Rd., Luzhu shiang, Taoyua County, Taiwan, R.O.C.
Tel:886-3-3223996 Fax:886-3-3228838 E-mail:mits.pacs@msa.hinet.net

2. ADMINISTRATIVE INFORMATION

K092581

2.1 510(k) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

General Information Establishment

OCT 30 2009

- Manufacturer: **MITSMED Medical Instrument Technology Co., Ltd.**
- Address: 4F-6, No. 99, Sec 1, NanKan Rd., Luzhu shiang, Taoyua County, 33858, Taiwan, R.O.C.
- Owner Number: **10026488**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hinet.net
  (official correspondent) 886-3-5208829 (Tel); 886-3-5209783 (Fax)
  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: August 12, 2009

Device Information

- **Proprietary Name:** MITS DICOM Gateway and Image Manager
- **Classification Name:** SYSTEM, IMAGE PROCESSING, RADIOLOGICAL, Class II
- **Regulation Number:** 892.2050
- **Product Code:** LLZ

Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to CSIST DICOM Gateway and Image Manager, **K012327.**
- **Device Description:**
  MITS DICOM Gateway and Image Manager is a suite of applications designed and produced by MITSMED Medical Instrument Technology CO., Ltd. It is a client-server based software system manages archiving, retrieving and displaying medical images. The DICOM converter application is **MITS DICOM Gateway.** The server side is **MITS Image Manager SERVER.** And the client side is **MITS Image Manager CLIENT.**

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- **Intended Use:**

  The MITS DICOM Gateway and Image Manager a device that captures 2 D images and data or receives images and data from various medical imaging sources (i.e. ultrasound system, R/F units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data (2 D or 3 D) can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

  Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

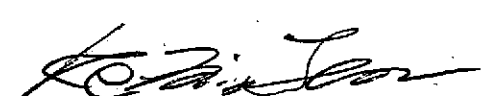
  To support the diagnostic interpretation of mammography studies, ImageSVR PACS will display the full fidelity DICOM image in a non-compressed format. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation.

- **Technological Characteristics**

  The MITS DICOM Gateway and Image Manager are a software server application and do not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to CSIST DICOM Gateway and Image Manager, **K012327.** Both of them have the same working principle and technologies. The differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. Besides, the submission contains the results of software validation that the risks analysis and the potential hazards have been classified Minor. Thus they are substantially equivalent.



Dr. Jen, Ke-Min
official correspondent for
MITSMED Medical Instrument
Technology Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MITSMED Medical Instrument Technology Co., Ltd
% Dr. Jen, Ke-Min
Official Correspondent
ROC Chinese-European Industry Research Society
No. 58, Fu Chiun Street, Hsin Chu City, 30067
TAIWAN ROC

OCT 30 2009

Re: K092581
Trade/Device Name: MITS DICOM Gateway and Image Manager
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 11, 2009
Received: October 21, 2009

Dear Dr. Jen, Ke-Min:

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 (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MITSMED Medical Instrument Technology Co., Ltd.
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Indications for Use

510(k) Number: K092581

Device Name: *MITSMED Medical Instrument Technology Co., Ltd.*

MITS DICOM Gateway and Image Manager

Indications for Use :

- The MITS DICOM Gateway and Image Manager is a device that captures 2 dimensional images and data or receives images and data from various medical imaging sources (i.e. ultrasound system, R/F units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data (2 dimensional or 3 dimensional) can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

  Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.
- To support the diagnostic interpretation of mammography studies the full fidelity DICOM image in a non-compressed format. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation.

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092581