CSIST

DEC 2 0 2001

K01 2327

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

October 12, 2001

Submitter's Information: 21 CFR 807.92(a)(1)

CSIST (Chung-Shan Institute of Science and Technology)
481 Chia-An Sec. Chung-Cheng Road
Chia-An Village, Lung Tan
32500; Taoyuan
Taiwan, R.O.C.

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	CSIST DICOM Gateway and Image Manager™ System
Common Name:	Frame Grabber and Viewing Workstation
Classification Name:	Picture Archiving and Communications System
Device Classification:	21 CFR 892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

Manufacturer	OLICON Imaging Systems, Inc.	A.L.I. Technologies, Inc
Device Name	OLICON 02 Workstation & PACS View Software	ALI 3D Tool Module for Medical Images
K Number	K973959	K003762
Decision Date	12/22/97	2/28/01
Product Code	90 LMD	90 LLZ
Classification	Class II	Class II

Device Description: 21 CFR 807 92(a)(4)

CSIST DICOM Gateway and Image Manager™ consists of three modules: A DICOM Gateway, Image Manager Server, and Image Manager Client.

- The DICOM Gateway captures (2D) images from a non-DICOM imaging modality, generates a DICOM medical image, and stores it in the CSIST Image Manager Server.
- The CSIST Image Manager Server accepts DICOM medical images (2D and 3D) from different acquisition modalities, stores these in the Image Archive and then transfers the generated images to the requested Image Manager Client.

- The Image Manager Server also has a "Performed Procedure Step Manager", which can issue a message to department system scheduler/order filler and the Image Manager Server, when the acquisition modality informs the Performed Procedure Step Manager that a specific procedure step has been started or completed.

Indications for Use: 21 CFR 807 92(a)(5)

The CSIST 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 systems, 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 professionals, including but not limited to physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does 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 printed.

Conclusion: 21 CFR 807 92(b)(1)

The two predicate devices (K003762 and K973959) and the new CSIST Gateway & Image Manager device are medical image PACS devices that are substantially equivalent in areas of design, general function, intended use, safety, and efficacy. Any differences between the two devices will not affect safety and effectiveness.

The CSIST DICOM Gateway & Image Manager is substantially equivalent to the OLICON 02 Workstation & PACS View Software (K973959) for image acquisition and image management for non-3D images and substantially equivalent to ALI 3D Tool Module (K003762) used with the ALI Ultra PACS for viewing and image management of 3D images.

The CSIST DICOM Gateway and Image Manager™ system has been and will be designed and manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The submission contains the results of a hazard analysis and all potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

CSIST
% Mr. Carl Alletto
Otech, Inc.
1100 Lakeview Blvd.
DENTON TX 76208

Re: K012327
Trade/Device Name: CSIST DICOM Gateway and Image Manager
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 14, 2001
Received: October 18, 2001

Dear Mr. Alletto:

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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

(Indications for Use Form)

510(k) Number: K012327

Device Name:

The CSIST DICOM Gateway/Image Manager™

Indications for Use:

The CSIST 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 systems, 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 professionals, including but not limited to physicians, nurses, and technicians.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

David A. Legerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012327