SEP 2 2 2005

TOTOKU K052199

510(k) SUMMARY

Submitter Information: TOTOKU ELECTRIC CO., LTD.
300 Oya, Ueda
Nagano 386-0192 Japan

Contact Person: Mikio Hasegawa, General Manager
Email: hasegawam@totoku.co.jp
Tel: +81.268.34.5469
Fax: +81.268.34.5565

Date Prepared: August 11, 2005

Device Name: 21.3-inch (54cm) Monochrome LCD Monitor MDL2115A (ME353i) (DV3MM-HB) (ME353iM)

Common Name: MDL2115A, ME353i, DV3MM-HB, ME353iM, 3M Monitor/Display

Classification Name: Class II
(Part892 Radiology Devices
Sec. 892.2050 Picture Archiving and Communication System)

Predicate Device: MDL2110A (K050485)

Device Description: MDL2115A (ME353i) (DV3MM-HB) (ME353iM) is a 21.3-inch Monochrome LCD monitor that supports DVI video signal and provides QXGA (1536 X 2048) resolution for both landscape and portrait display.

Intended Use: 21.3-inch (54cm) Monochrome LCD Monitor MDL2115A (ME353i) (DV3MM-HB) (ME353iM) is to be used in conjunction with the picture archiving communication system (PACS) for medical imaging applications. It is not meant to be used for digital mammography.

Substantial Equivalence: MDL2115A (ME353i) (DV3MM-HB) (ME353iM) has almost the same characteristics as TOTOKU's predicate device MDL2110A (K050485) except for a LCD panel, an inverter and chassis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administrati
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2005

Mr. Mikio Hasegawa
General Manager
Totoku Electric Co., Ltd.
MM Company, Design Group
300 Oya, Ueda, Nagano, 386-0192
JAPAN

Re: K052199
Trade/Device Name: 21.3-inch (54cm) Monochrome LC
Monitor MDL2115A (ME353i) (DV3MM-HB) (ME353
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 11, 2005
Received: August 12, 2005

Dear Mr.Hasegawa:

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

TOTOKU

INDICATIONS FOR USE

510(k) Number: Not Known

Device Name: 21.3-inch (54cm) Monochrome LCD Monitor MDL2115A (ME353i) (DV3MM-HB) (ME353iM).

Indications for use:

21.3-inch (54cm) Monochrome LCD Monitor MDL2115A (ME353i) (DV3MM-HB) (ME353iM) is to be used in conjunction with the picture archiving communication systems (PACS) for medical imaging applications. It is not meant to be used for digital mammography.

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 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 K052199