K012099

JUL 3 1 2001

510(k) Summary
as required by 807.92

1. Company Identification

Totoku Electric Co., Ltd.
300 Oya, Ueda-shi, Nagano-ken , 386-0192, Japan
Tel : 011-81-268-34-5484
Fax : 011-81-268-34-5565

2. Official Correspondent

Mikio Hasegawa (Mr.)
Manager
Design Group

3. Date of Submission

June 7, 2001

4. Device Trade name

Monochrome perfectly flat panel displays, ME Series

5. Common Name

Monitor, display, workstation, and others

6. Classification

Medical displays were classified in Class II per 21 CFR 890.2050.

7. Predicate Device

BARCO MGD 221 2 MegaPixel Diagnostic Display, manufactured by
BARCO NV / Display Systems (K000923). Comparison of the principal characteristics of the three devices which are pertinent to clinical performance is shown in Appendix 1.

8. Description of Device

The ME Series Medical Displays are displays for medical use.
This product complies with Radiation performance standards (21 CFR Chapter I, Sub-chapter J).

9. Intended Use

The ME Series Medical Displays are intended for use with Picture Archiving Communication Systems (PACS) for medical imaging applications by physicians.

10. Explanation of ME Series

ME Series consists of the following models.

ME221f (Model No. MDT 2205A)
ME222f (Model No. MDT 2210A)
ME223f (Model No. MDT 2212A)
ME224f (Model No. MDT 2210A)
ME521f (Model No. MDT 2209A)
ME311L (Model No. MDL 2102A)

Comparison of specifications is shown in Appendix 2.

11. Compliance standards

Medical safety: UL2601-1, CSA No.601-1, IEC60601-1,
MDD/CE (EN60601-1)

EMC: MDD/CE (EN60601-1-2), FCC-A, VCCI-A, IEC60601-2

Others: DHHS

Appendix 1: Comparison table with predicate device

Item	ME221f/4	MGD221
510(k) Number	Not known	K000923
Display area	Horizontal 300mm, vertical 400mm	300mm × 400mm
Luminescent material	P45 (standard) or P4 (optional)	B4-L8
Input signal	Video signal – analog 0.714Vp-p/75 Ω Synchronizing signal – 1.0-5.5Vp-p/3.9k Ω Synchro input – Separate/composite/ composite video. Connector – BNC and SD-sub 15p (VGA connection, Gch for video)	●Signal inputs Video input connector tye: BNC Video input voltage: 0.7 Vpp Termination: 75 Ω ●Synchronization inputs Inputs provided: CS or HS and VS Input connector type: BNC Termination: 75 Ω Sync input voltage: nominal 0.5Vpp
Maximum display pixels	1200 dots x 1600 line	1280 dots x 1600 line
Scanning frequency	Horizontal 30k-127kHz, vertical 50-180Hz	Horizontal 80-140kHz, Vertical 48-150Hz
Maximum image clock	250MHz	250MHz
Maximum luminance	410 cd/m^2 min. (P4 luminescent material) for both partial white (20%) and total white (100%)	Calibrated: 222cd/m^2; 65fL Peak: 360cd/m^2; 105fL
Luminance calibration	Software (standard item) Photosensor (optional item) – DTP92 (X-Lite)	Frontal X-Rite DTP92
Serial communication connector	D-sub 9p x 2	1 input, 1output 9600 baud, RS232 SUB-D9 male/female connector Operational at save state
Agency standards	Medical safety: UL2601-1, CSA No.601-1, IEC 60601-1, MDD/CE (EN60601-1) Others: DHHS	Medical safety: UL2601-1, cUL2601-1, IEC 60601-1, CE (EN60601-1) Others: DHHS
Dimensions and weight (incl. tilt and swivel)	Net, 412 x 578 x 518 mm (W x H x D) 35kg Packed, 560 x 710 x 730 mm (W x H x D) 41kg	Unpacked, 400 x 561 x 558 mm, 37.4kg Packed, 630 x 780 x 788 mm, 55.9 kg
Power supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

Appendix 2 Comparison table among application models

Item	ME221f	ME222f	ME521f
510(k) Number	Not known	Not known	Not known
Display area	Horizontal 300mm, vertical 400mm	Horizontal 400mm, vertical 300mm	Horizontal 302mm, vertical 378mm
Luminescent material	P45 (standard) or P4 (optional)	P45 (standard) or P4 (optional)	P45 (standard) or P4 (optional)
Input signal	Video signal – analog 0.714Vp-p/75Ω Synchronizing signal – 1.0-5.5Vp-p/3.9kΩ Synchro input – Separate/composite/composite video. Connector – BNC and SD-sub 15p (VGA connection, Gch for video)	Video signal – analog 0.714Vp-p/75Ω Synchronizing signal – 1.0-5.5Vp-p/3.9kΩ Synchro input – Separate/composite/composite video. Connector – BNC and SD-sub 15p (VGA connection, Gch for video)	Video signal – analog 0.714Vp-p/50Ω or 75Ω (optional) Synchronizing signal – TTL level, negative Synchro input – Separate. Connector – BNC
Maximum display pixels	1200 dots x 1600 line	1600 dots x 1200 line	2048 dots x 2560 line
Scanning frequency	Horizontal 30k-127kHz, vertical 50-180Hz	Horizontal 30k-110kHz, vertical 50-180Hz	Horizontal 186kHz, vertical 71Hz (fixed)
Maximum image clock	250MHz	250MHz	500MHz
Maximum luminance	410 cd/m² min. (P4 luminescent material) for both partial white (20%) and total white (100%)	600 cd/m² min. (P45 luminescent material) for both partial white (20%) and total white (100%)	600 cd/m² min. (P45 luminescent material) for both partial white (20%) and total white (100%)
Luminance calibration	Software (standard item) Photosensor (optional item) – DTP92 (X-Lite)	Software (standard item) Photosensor (optional item) – DTP92 (X-Lite)	Software (standard item) Photosensor (optional item) – DTP92 (X-Lite)
Serial communication connector	D-sub 9p x 2	D-sub 9p x 2	D-sub 9p x 2
Agency standards	Medical safety: UL2601-1, CSA No.601-1, IEC 60601-1, MDD/CE (EN60601-1) Others: DHHS	Medical safety: UL2601-1, CSA No.601-1, IEC 60601-1, MDD/CE (EN60601-1) Others: DHHS	Medical safety: UL2601-1, CSA No.601-1, IEC 60601-1, MDD/CE (EN60601-1) Others: DHHS
Dimensions and weight (incl. tilt and swivel)	Net, 412 x 578 x 518 mm (W x H x D) 35kg Packed, 560 x 710 x 730 mm (W x H x D) 41kg	Net, 505 x 500 x 515 mm (W x H x D) 35kg Packed, 615 x 655 x 650 mm (W x H x D) 40kg	Net, 412 x 578 x 552 mm (W x H x D) 35kg Packed, 560 x 710 x 730 mm (W x H x D) 41kg
Power supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

Item	ME223f*1	ME224f*2
510(k) Number	Not known	Not known
Display area	Horizontal 300mm, vertical 400mm	Horizontal 400mm, vertical 300mm
Luminescent material	P45 (standard) or P4 (optional)	P45 (standard) or P4 (optional)
Input signal	Video signal – analog 0.714Vp-p/75Ω Synchronizing signal – 1.0-5.5Vp-p/3.9kΩ Synchro input – Separate/composite/composite video. Connector – BNC and SD-sub 15p (VGA connection, Gch for video)	Video signal – analog 0.714Vp-p/75Ω Synchronizing signal – 1.0-5.5Vp-p/3.9kΩ Synchro input – Separate/composite/composite video. Connector – BNC and SD-sub 15p (VGA connection, Gch for video)
Maximum display pixels	1200 dots x 1600 line	1600 dots x 1200 line
Scanning frequency	Horizontal 30k-127kHz, vertical 50-180Hz	Horizontal 30k-110kHz, vertical 50-180Hz
Maximum image clock	250MHz	250MHz
Maximum luminance	800 cd/m² min. (P4 luminescent material) for both partial white (20%) and total white (100%)	600 cd/m² min. (P45 luminescent material) for both partial white (20%) and total white (100%)
Luminance calibration	Software (standard item) Photosensor (optional item) – DTP92 (X-Lite)	Software (standard item) Photosensor (optional item) – DTP92 (X-Lite)
Serial communication connector	D-sub 9p x 2	D-sub 9p x 2
Agency standards	Medical safety: UL2601-1, CSA No.601-1, IEC 60601-1, MDD/CE (EN60601-1) Others: DHHS	Medical safety: UL2601-1, CSA No.601-1, IEC 60601-1, MDD/CE (EN60601-1) Others: DHHS
Dimensions and weight (incl. tilt and swivel)	Net, 412 x 578 x 518 mm (W x H x D) 35kg Packed, 560 x 710 x 730 mm (W x H x D) 41kg	Net, 505 x 500 x 515 mm (W x H x D) 35kg Packed, 615 x 655 x 650 mm (W x H x D) 40kg
Power supply	100-240V AC, 50/60Hz	100-240V AC, 50/60Hz

NOTE

*1 ME223f is identical to ME221f except for CRT focus.

*2 ME224f is identical to ME223f except for luminance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Totoku Electric Co., Ltd.
% Mr. Shinichi Yamanaka
Safety Dept.
Cosmos Corporation
319 Akeno, Obata-cho, Watarai-gun
Mie-ken, 519-05 JAPAN

Re: K012099
ME Series Medical Display
Dated: June 7, 2001
Received: July 5, 2001
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Yamanaka:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 (s)

510(k) Number (If known): Not known K012099

Device Name: Monochrome perfectly flat panel display, ME Series

Indications for Use:

The ME Series Medical Displays are intended for use with Picture Archiving Communication Systems (PACS) for medical imaging applications by physicians.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012099