

510(k) Summary of Safety and Effectiveness

The following summary is submitted pursuant to 21 CFR 807.92:

FEB 27 1998

- [1] Submitter:** Marquette Medical Systems
E for M Imaging Systems Division
625 Alaska Avenue
Torrance, CA 90503 USA
- Date Prepared:** November 26, 1997
- [2] Trade/Proprietary Name:** EPS
Common/Usual Name: R/F Digital Image Acquisition and Review System
Classification: Class II per 21 CFR 892.1620
Classification Name: (Accessory to) Cine or Spot Fluorographic X-Ray Camera
Panel: Radiology
Performance Standards: 21 CFR 1020.10, Performance Standards for Ionizing Radiation Emitting Products;
21 CFR 1040.10, Performance Standards for Light-Emitting Products;
DICOM 3.0 Standard for Digital Exchange Media (Voluntary);
UL 2601.1, Standard for Safety, Medical Electrical Equipment, Part 1: General Requirements for Safety [Underwriters Laboratories] (Voluntary);
UL 1950, Safety of Information Technology Equipment, Including Electrical Business Equipment [Underwriters Laboratories] (Voluntary);
SMPTE (Society of Motion Picture and Television Engineers) Test Patterns (Voluntary)
- Reason for 510(k):** New product equivalency.
- [3] Predicate Device:** EPS-20, K922240, manufactured by Toshiba America Medical Systems, Inc.

[4] Description:

The Electronic PhotoSpot (EPS) is a 10 bit PC based multitasking acquisition/display system configured for use in R/F applications. This system is designed for use by a qualified Radiologic Technologist or Radiologist.

More specifically, the EPS system is a digital recording system designed for use as an electronic photospot device on OEM manufactured R/F systems. This system consists of independent and simultaneous acquisition of data, review, post processing of raw data and archive transfer functions. The system is modular in configuration allowing single and dual room configurations for acquisition and/or review. The system has 10 bit, 1024 x 1024 digital acquisition, display and storage capability and uses a Windows based operator interface on the Operator Console/Review Station. It includes the following major components (minimally):

- a. Pentium computers
- b. Image monitor(s)
- c. Camera X-Ray Interface
- d. MOD media for archival
- e. Software program developed by Marquette Medical Systems to run in conjunction with Microsoft Windows NT

The EPS provides image acquisition, display, archival, and exchange media compliant with the DICOM 3.0 standard. Furthermore, the EPS allows connection to the medical facility's existing LAN network for data dissemination to support reviews, reports, and patient billing.

The following questions have been addressed:

- Is the device life supporting or life sustaining? No
- Is the device implanted (short term or long term)? No
- Does the device design use software? Yes
- Level of concern for software (if applicable)? Minor
- Is the device sterile? No
- Is the device for single use? No
- Is the device for home use or prescription use? No
- Does the device contain drugs or biological products as a component? No
- Is the device a diagnostic kit? No

[5] Intended Use:

The EPS system is a digital recording system designed for use as an electronic photospot device on OEM manufactured Radiographic & Fluoroscopic ("R/F") systems. The system is modular in configuration allowing single and dual room configurations for acquisition and/or review, providing assistance to Radiologists and Radiologic Technologists in routine diagnostic examinations and special procedures in R/F. The EPS system may be used to acquire, display, record, archive, and disseminate digital R/F image data.

[6] Comparison to Predicate Devices:

The Toshiba EPS-20 is a legally marketed predicate device with the same intended use as Marquette Medical Systems' EPS System. The Toshiba EPS-20 was successfully cleared through the FDA's premarket notification process under file number K922240. A comparison of device specifications and principles of operation indicates no new questions of safety or efficacy, or substantial risk are raised.

Official Correspondent: Stu Bush

Signature:  11/26/97

Telephone: (310) 320-8334
Fax (310) 618-9031



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Stu Bush
Director, Regulatory Affairs & Quality Assurance
Official Correspondent
Marquette Medical Systems
625 Alaska Avenue
Torrance, CA 90503-5124

Re: K974504
EPS (R/F Digital Image Acquisition and
Review System
Dated: November 26, 1997
Received: December 1, 1997
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA/90 LLZ

Dear Mr. Bush:

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 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) 594-4613. 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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: _____

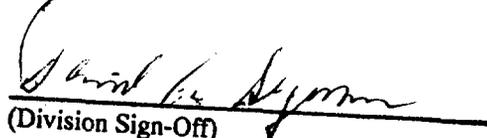
Indications For Use:

B. INTENDED USE

The EPS system is a digital recording system designed for use as an electronic photospot device on OEM manufactured Radiographic & Fluoroscopic ("R/F") systems. The system is modular in configuration allowing single and dual room configurations for acquisition and/or review, providing assistance to Radiologists and Radiologic Technologists in routine diagnostic examinations and special procedures in R/F.

(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, ENT,
and Radiological Devices

510(k) Number K974504

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)