

K970680

JUN 20 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

The 510(k) premarket notification for the GLORY mammography system describes a modification of the legally marketed MAM-CH22S mammography system (K960381).

The intended use and the indications of use of the GLORY mammography system are identical to those of the MAM-CH22S mammography system.

The effectiveness of the GLORY mammography system is significantly equivalent to that of the MAM-CH22S mammography system. Compared to the MAM-CH22S mammography system, additional radiation (or mAs) is provided for very thick or dense breasts and higher mA values are provided with the small focal spot for magnification procedures.

With regards to safety, the GLORY mammography system was designed to comply with International Standard IEC (International Electrotechnical Commission) 601-1, Medical Electrical Equipment, Part 1: General Requirements For Safety. The modifications were analyzed and preventive measures were taken.

Based on this analysis, to the best of our judgment, the GLORY mammography system does not introduce new significant risks that could cause a safety hazard.

Based on the above, it is Elscint's opinion that the GLORY mammography system is substantially equivalent in safety and effectiveness to the legally marketed device, MAM-CH22S.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Beny Sherer
Safety Officer
Elscont, Inc.
Service Headquarters
86 Orchard Street
Hackensack, NJ 07601

Re: K970680
Glory Mammography System
Dated: May 15, 1997
Received: May 16, 1997
Regulatory class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Sherer:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/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): K970680

Device Name: GLORY Mammography System

Indications For Use:

Radiography of the breast

(Please do not write below this line-continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation(ODE))

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

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970680