

DEC 11 1998

Elscent, Inc.

Corporate Headquarters

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K983313

510(k) Summary

This 510(k) Summary provides the information required by 21 CFR 807.87(h).

1. Submitter's Name and Address:

Elscent Inc., 22 Paris Avenue, Rockleigh, NJ 07647

Contact Person and Telephone No.:

Steven M. Kay, Director, Regulatory Affairs and Quality Assurance, (201) 750-3240.

Date of Summary:

17 September 1998

2. Product Identification

Trade/Proprietary Name:

Advanced Automatic Detector Selection (AADS) option for the GLORY

Common Name: Option

Classification Name:

Mammographic X-Ray System (21 CFR 892.1710/Procode: 90 IZH)

3. Predicate Device(s):

GLORY (K970680) mammography system

4. Device Description:

The Advanced Automatic Detector Selection (AADS) option is used with the automatic exposure control of the GLORY mammography system. With the AADS option, the legally marketed GLORY system can determine exposure parameters automatically from a detector located beneath the densest breast tissue.

5. Intended Use:

The intended use and the indications for use of the GLORY mammography system (Screening and diagnostic breast radiography) are unchanged.

6. Safety and Effectiveness:

The GLORY is designed to comply with IEC Electrical (601-1) and Mechanical (601-2) international standards. Potential electrical, mechanical, radiation and software hazards are identified through hazard analysis. Product safety and quality are maintained by:

- Adherence to Federal and International standards
- System verification and validation, continuing review of user requirements and the implementation of a Quality System that conforms to Federal QSR and ISO requirements.

To the best of our judgement, the ADDS option does not result in any new potential safety risks and does not significantly change the effectiveness of the GLORY system.

7. Equivalency Information Summary:

It is the opinion of Elscent, Inc. that the ADDS option is of a comparable type and substantially equivalent to the currently marketed GLORY mammography system.

Elscent



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Steven M. Kay
Director of Regulatory Affairs
Elscinf, Inc.
22 Paris Avenue
Rockleigh, NJ 07647

Re: K983313
Advanced Automatic Detector Selection Option for
Glory Mammography System (ADDS Option)
Dated: September 18, 1998
Received: September 21, 1998
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Kay:

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/cdrf/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: Advanced Automatic Detector Selection Option for GLORY Mammography System

Indications For Use:

- Radiography of the breast
- Preoperative wire localization and stereotactic biopsy procedures

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

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

David A. Segerson

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K983313

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)