 OCT 2 4 2001 K013290

1.3 Safety and Effectiveness 510(k) Summary

1. The Modified 650 Mammography System has been designed for classification to Underwriters Laboratories, Inc. (UL) to Standard 187.

2. The Modified 650 Mammography System has been designed for classification by Underwriters Laboratories, Inc. to Canadian Standards Association, CSA Standard C22.2 No. 114.

3. The Modified 650 Mammography System has been designed for certification to International Electrotechnical Commission Standard IEC-601-1

4. The Modified 650 Mammography System is tested and conforms to the Federal Performance Standards for Ionizing Radiation Emitting Products, defined in 21 CFR 1000.

5. The American College of Radiology (ACR) in Reston, Virginia, conducts a nationwide program that accredits providers of mammography services. To qualify for ACR accreditation, the mammography device at a provider site must meet ACR standards for image quality and operation within radiation dose limits. The Modified 650 Mammography System has been designed to meet the requirements for ACR accreditation.

6. A comprehensive Operator's Manual provided with each system is user friendly and comprehensive, thus ensuring safe and effective operation of the Modified 650 Mammography System.

This information is provided pursuant to the requirements of the Safe Medical Devices Act of 1990 (SMDA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

Ms. Roaida Rizkallah
Regulatory Specialist
LORAD Hologic Company
36 Apple Ridge Road
DANBURY CT 06810

Re: K013290
Trade/Device Name: Affinity System
(Modified 650 Mammography System)
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray System
Regulatory Class: II
Product Code: 90 IZH
Dated: October 1, 2001
Received: October 2, 2001

Dear Ms. Rizkallah:

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/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

510(k) Number (if known): K013290

Device Name: Modified 650 Mammography System

Intended Use:

The Modified 650 Mammography System is intended to produce radiographic images of the breast. Its specific intended use is for screening and diagnostic mammography. Screening mammography involves the production of images for initial examination for breast cancer diagnosis. Diagnostic mammography includes the production of magnified images for more thorough examination of areas of the breast determined suspicious through screening mammography, special views, spot compression views, and the production of images used by a physician in preparation for biopsy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___
21 CFR 801.109

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013290