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K030666

1.3 Safety and Effectiveness 510(k) Summary

1. The Multicare Platinum has been designed for classification to Underwriters Laboratories, Inc. (UL) to Standard 2601-1

2. The Multicare Platinum has been designed for classification by Underwriters Laboratories, Inc. to Canadian Standards Association, CSA Standard C22.2 No. 601.1-M9

3. The Multicare Platinum has been designed for certification to International Electrotechnical Commission Standard IEC-601-1

4. The Multicare Platinum is tested and conforms to the Federal Performance Standards for Ionizing Radiation Emitting Products, defined in 21 CFR 1020

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 Multicare Platinum 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 Multicare Platinum

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

MAR 2 5 2003

Ms. Gail Yaeker-Daunis
Sr. Quality/Regulatory Specialist
Lorad, A Hologic Company
36 Apple Ridge Road
DANBURY CT 06810

Re: K030666
Trade/Device Name: MultiCare Platinum System and Accessories
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: February 27, 2003
Received: March 3, 2003

Dear Ms. Yaeker-Daunis:

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 Section 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 the 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" (21CFR Part 807.97) you may obtain. 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): K030666

Device Name: **Multicare Platinum**

Intended Use:

The MultiCare Platinum device combines the function of a standard x-ray mammography unit with that of a stereotactic lesion localization system to produce a device that has specific application in first localizing, and then giving a physician the capacity of performing Fine Needle Aspiration or core biopsy of lesions determined to be suspicious through prior mammographic examination.

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 K030666