Summary of Safety and Effectiveness

K040884

APR 2 3 2004

Submitter: Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

Contact Person: Gail Yaeker-Daunis
Sr. Regulatory Specialist

Date Prepared: April 1, 2004

Common Name: DSM

Proprietary Name: Digital Spot Mammography System

Predicate Devices: Lorad DSM **K921962A** & **K030666**

Intended Use: DSM as part of a standard x-ray mammography unit is part of a stereotactic lesion localization system that has the application of localizing, and then giving a physician the capability of performing fine needle aspiration or core biopsy of lesions determined to be suspicious through prior mammographic examination

Compliance Statement:

The DSM has been designed for certification to International Electrotechnical Commission Standard IEC-601-1, IEC 601-1-x, IEC 601-2-xx

cUL 187, UL 1950, FCC-A, DHHS, CSA-950, IEC 950

A comprehensive Operator's Manual provided with each system is user friendly and comprehensive, thus ensuring safe and effective operation of the DSM.

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

Section 1.0 General Information K040884

1.1 Introduction

The purpose of this Special 510(k) is to modify the **L**orad **D**igital Spot **M**ammography System which was originally cleared for market as 510 (k) # **K921962A** At that time, **DSM** was cleared for use on the Lorad Mammography systems and the Lorad StereoGuide Stereotactic Breast Biopsy System for use in localization and stereotactic procedures.

DSM was last modified as part of the Lorad MultiCare Platinum System (formerly StereoGuide) with Digital Spot Mammography as 510 (k) # **K030666**.

At this time, Lorad wishes to modify **DSM** to include DICOM capabilities and to provide capability for use with both the MultiCare Platinum Breast Biopsy System and Lorad Mammography Systems.

1.2 Indications for Use

The indications for use of the **DSM** are the same as submitted in the Lorad MultiCare Platinum System, 510 (k) # **K030666**, and repeated below:

DSM as part of a standard x-ray mammography unit is part of a stereotactic lesion localization system that has the application of localizing, and then giving a physician the capability of performing fine needle aspiration or core biopsy of lesions determined to be suspicious through prior mammographic examination.

1.3 Substantial Equivalence

The **DSM** and the predicate device DSM as cleared in MultiCare Platinum 510(k) # **K030666** have the same intended use, the same general configuration, the same principles of operation, and similar operating parameters. The **DSM** is now available for use with both Lorad MultiCare Platinum Breast Biopsy Table System and M-IV Mammography System. The addition of DICOM capability is considered the only significant change to the device.

DSM is comprised of a workstation, monitor, trackball, keyboard, computer and digital image receptor.

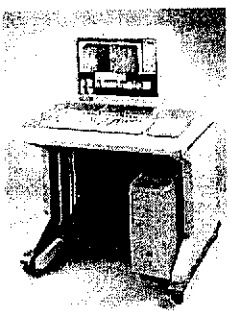

Table 1 below compares the current DSM to the predicate DSM cleared on February 27, 2003 as 510(k) # **K030666.**

DSM Console	**DSM (K030666) Lorad Multicare Platinum**	**DSM**
Tissue Imaging Area	5.0 cm x 5.0 cm Operator control of Image contrast & luminance: Choice of 512 or 1024 pixel resolution Large 18 in., high resolution, gray scale flat screen monitor	Same
Near Real-Time Image Display	512 Mode – approx. 4 seconds 1024 Mode – approx 8 seconds	Same
Image Device	Charge-Coupled Device (CCD)	Same
Monitor	Flat Panel	Same
Display Area	18 in. diagonal (minimum) 160° viewing angle (minimum)	Same
Computer Microprocessor	Intel CPU	Same
Archive Media	DVD + R/RW, CD – R/RW	Same
Operating System	Operating system will only recognize disks, DVD/CD formatted with DOS, Windows 9X/NT/2000	Same
User Controls	Power, Brightness, Contrast, Picture Tilt, Height Vertical Position, Horizontal Position	Same

DSM Console	DSM (K030666) Lorad Multicare Platinum	DSM
Approvals	UL 1950, FCC-A, DHHS, CSA-950, IEC 950	Same
DICOM	DICOM Query/Retrieval Operations	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2004

Ms. Gail Yaeker-Daunis
Sr. Regulatory Specialist
Hologic, Inc.
36 Apple Ridge Road
DANBURY CT 06810

Re: K040884
Trade/Device Name: Lorad Digital Spot Mammography System (DSM)
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: April 2, 2004
Received: April 6, 2004

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 such 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): K040884

Device Name: Lorad Digital Spot Mammography System **(DSM)**

Indications for Use:

DSM as part of a standard x-ray mammography unit is part of a stereotactic lesion localization system that has the application of localizing, and then giving a physician the capability 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

David A. Lepmm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040884