

K964069

# SIEMENS

## 510 (k) SUMMARY

### I. GENERAL INFORMATION:

#### Establishment:

• Address: Siemens Medical Systems, Inc.  
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 Iselin, NJ. 08830

MAY - 8 1997

• Registration Number: 2240869

• Contact Person: Kathleen Rutherford  
 Manager, Regulatory Submissions  
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#### Date of Summary Preparation:

#### Device Name:

• Trade Name: OPDIMA Mammographic X-ray System  
 Mammomat 3000 with DSBAS  
 (Digital Stereotactic Attachmant System)

• Common Name: Mammographic X-ray System

• Classification Name: Mammographic X-ray System

• Classification: Class II

Performance Standards: 21 CFR, Subchapter J

All system components to which the above standard applies are certified to conform with 21 CFR subchapter J

### II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.

#### Device Description:

The fully functional OPDIMA mammographic x-ray system configuration consists of the commercially available Mammomat 3000 mammographic x-ray system configured with the DSBAS (Digital Stereotactic Biopsy Attachment System) option. The Mammomat 3000 with DSBAS option is a Digital Stereotactic Biopsy Mammography System intended for use in small field digital mammographic examinations. The Mammomat 3000 with the DSBAS option consists of the Mammomat 3000 stand and generator configured with a camera assembly, i.e., CCD detector, biopsy unit and a workstation for the display and processing of images,

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modem, MO drive, trolley, Biopsy controller and DSBAS software (Application Software and Biopsy Controller software).

The user can select three modes of operation, Spot, biopsy or normal (non-digital) mode. The system is designed with key image processing functions, Zoomfactor, Magnifying Glass, Contrast Enhancement, Image invert, Histogram, Electronic ruler and image filter. Zoomfactor and Magnifying glass provide 2x, 4x and 8x magnification. For image filtering, five image filters are selectable. The Histogram feature displays the population for each grey scale value.

## **Intended Use:**

The Siemens Digital Stereotactic Biopsy Attachment System (DSBAS) marketed as OPDIMA (Optimized Digital Mammography) is a digital small field x-ray option for the commercially available Mammomat 3000 mammographic x-ray system. The Mammomat 3000 with DSBAS option is intended for use in small field mammographic x-ray imaging. Such small field imaging is used during stereotactic biopsy and spot localization.

## **Technological Characteristics:**

The DSBAS mammographic X-ray system consists of the Mammomat 3000 configured with the DSBAS (Digital Stereotactic Biopsy Attachment System) Option. The major system components consist of the Mammomat 3000 X-ray stand and generator, CCD detector, biopsy unit, Biopsy controller, DSBAS system software and workstation. The CCD detector has an imaging area of 49 x 85 mm. The pixel sizes vary according to the mode of operation; 24  $\mu\text{m}$  in spot mode and 48  $\mu\text{m}$  in stereo mode. The pixel matrices are 2048 x 3584 pixel in spot mode and 1024 x 1792 pixel in stereo mode with a pixel depth of 12 bits. The image resolution is  $\geq 10$  lp/mm in stereo mode and  $\geq 11$  lp/mm in spot mode.

The DSBAS workstation is a 32 bit, 140 Mhz processor with 64 MB RAM, 32 kB and 2GB hard disk. The monitor has a resolution of 1024 x 1280 with 8-bit pixel depth. The system is equipped 2GB hard disc for archiving of approximately 500 images and optional disc archiving of 2.6 GB (250 images in spot mode and 1000 images in biopsy mode) per additional disc.

## **General Safety and Effectiveness Concerns:**

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

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## Substantial Equivalence:

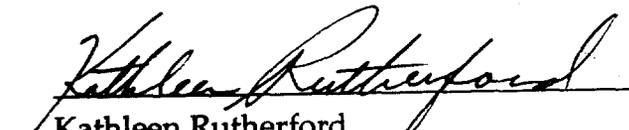
In the opinion of Siemens Medical Systems, Inc., Mammomat 3000 with the DSBAS option is of comparable type and substantially equivalent to the following currently marketed Small Field Digital Mammographic X-ray Systems:

### Predicate Device

Mammovision  
DSM

### Manufacturer

Fischer Imaging, Inc.  
Lorad, Inc.

  
Kathleen Rutherford  
Manager, Regulatory Submissions

10/8/96  
Date