K973651

## Section Seven - 510(k) Summary

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### 7.1 Submitter

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### 7.2 Device Identification

M-IIIE Mammography System
Mammographic X-ray System 21 CFR 892.1710

Legally Marketed Device to Which Substantial Equivalance is Claimed: Lorad M-III Mammographic X-ray System and Lorad M-IV Mammographic X-ray System.

### 7.3 Device Description

#### 7.3.1 Intended Use

The Lorad M-IIIe Mammography System is intended to produce radiographic images of the breast. Its specific intended use is 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.

#### 7.3.2 Design

The Lorad M-IIIe mammography system is based on Lorad's currently marketed M-III, with changes to add features of Lorad's M-IV. The mechanical package, layout and basic electrical design of the M-III are used, but the x-ray tube of the M-IV, as well as the M-IV user interface and several M-IV software feature algorithms are incorporated. The changes made to the M-III to create the M-IIIe are summarized in the table below.

| M-III Specification | Change | M-IIIe Result |
|---|---|---|
| CRT Display and custom keypads for user interface | LCD panel display and standard QWERTY keyboard for user interface | User interface duplicates the Lorad M-IV |
| Separate unit suspended on an attached shelf flashes identification data onto the film | Film flasher unit built into frame and covers of the mammography unit. | Film flashing function now integrated into the unit package |
| Automatic Exposure Modes:<br>• Auto-Time<br>• Auto-kV | Automatic Exposure Modes:<br>• Auto-Time<br>• Auto-kV<br>• Auto-Filter | Automatic exposure modes include the filter selection (Mo or Rh) capability employed in the M-IV |
| X-ray Tube: .1/.3 mm focal spots; 16° target angle. | X-ray Tube: .1/.3 mm focal spots 10° target angle small focal spot, 16 degree target angle large focal spot. | Increases small focal spot tube current capability from 20 mA to 28 mA. |
| Automatic Exposure Detector:<br>• Single cell | Automatic Exposure Detector:<br>• Averaged over three separate cells | Greater area of tissue sampled for controlling exposure density. |
| Only Compression Thickness indicated | Compression Thickness and compression force indicated with digital display. | Meets MQSA/ACR requirements |
| Light Field Mirror in x-ray path during exposure | Light Field mirror removed from x-ray path during exposure | Removes source of artifacts and eliminates effects on beam characteristics |

### 7.3.3 Construction

The Lorad M-IIIe is a stand alone mammography device, mounted on a base with casters which allow positioning in the room where it is installed. A foot-operated mechanical lock prevents movement during clinical use of the device. The unit is AC powered, and must be connected to a 220 VAC/50-60 hertz (nominal) line to operate.

The standalone unit has two major assemblies: the C-arm and the Control Console. An M-IIIe configuration tree, identifying the major components and subassemblies that comprise the M-IIIe, is provided in Attachment 1. The C-arm, which contains an x-ray tube, an image receptor support, compression device, a beam limiting device, switches that actuate the C-arm functions, and sensors for detecting installed accessories and making radiation measurements, is attached to the front (patient side) of the machine. The C-arm frame is constructed of two vertical steel rails, which are precision machined to accept the components which it supports. Molded plastic covers enclose the x-ray tube, which is purchased from OEM manufacturers, and the beam limiting device, while aluminum covers enclose the sides, back, top and bottom of the C-arm framework. The bottom panel of the C-arm is spring loaded and attached to a safety switch which disables C-arm vertical movement downward should it contact an object, such as a wheelchair.

The C-arm is attached by a locking pivot mechanism to the Control Console. The pivot allows the C-arm to be manually rotated about its central axis. The

pivot mechanism is attached to the control console via a vertically moving carriage. This carriage is capable of movement in the vertical direction, driven by an AC motor and a drive screw mounted to the base of the Control Console. The pivoting action of the C-arm is locked by an electromagnetic brake attached to the vertical carriage, which, in its unactuated condition, prevents rotation. The brake must be electrically actuated to release the C-arm for movement. The Control Console is constructed of a welded steel frame, to which the electrical assemblies and components of the unit are mounted. At the top of the Control Console, an operator station, consisting of a keyboard, a panel of individual pushbuttons and a Liquid Crystal Display (LCD) are mounted. Steel and aluminum panels enclose the Control Console. At the rear of the Control Console, opposite the operator station, there is a input power connector and input circuit breaker.

### 7.3.4 Compatible Equipment

The M-IIIe is equipped with accessories necessary in the performance of mammography. Bucky grid accessories, containing either conventional linear or air-interspaced High Transmission Cellular grids, and a motor system to move the grid during exposure, are provided to reduce the effects of scattered radiation on the image. Compression plates to accommodate different sized patients and different mammographic applications are supplied and are interchangeable by the operator. A magnification table is provided, which provides a means to obtain geometrically enlarged views of suspicious areas of the breast. Footswitches are provided that operate (1) the C-arm vertical position function, to place the breast platform appropriately to the patient's height, and (2) the compression function, allowing the operator to use both hands to position the patient while applying and releasing breast compression position the patient while applying and releasing breast compression.

The M-IIIe is capable of use with Lorad's StereoLoc II Breast Biopsy system which was separately cleared by FDA. Use of the M-IIIe with the StereoLoc does not alter the operation of the M-IIIe..

### 7.3.5 Physical and Functional Specifications

#### 7.3.5.1 Electrical Input

| | |
|---|---|
| Mains Voltage: | 200/208/220/230/240 VAC nominal, ±10%, 50/60 Hz |
| Mains Impedance: | Maximum line impedance not to exceed 0.25 ohms |

Maximum Power Consumption:

4.4 KVA for 5 seconds duration

| | |
|---|---|
| Standby Power: | 0.50 KVA nominal |

Maximum Line Current:

25 amps for 5 seconds

Circuit Breaker Rating:

15A, time delay curve to allow for inrush currents (200% overload for 7 seconds)

| | |
|---|---|
| Duty Cycle: | Full load 5 seconds on, 30 seconds off (1:7) |

#### 7.3.5.2 Dimensions

| | |
|---|---|
| Height: | 77 inches (196 cm.) |
| Width: | 60.25 inches (64.7 cm.) |
| Depth: | 25.5 inches (153 cm.) |
| Weight: | 700 lb. (317.5 kg) approximate |

#### 7.3.5.3 Operating Environment

Temperature Range:

10° C. to 40° C.

Relative Humidity Range:

30% to 75% non-condensing

ESD Susceptibility:

Level of 3 kV for contact discharge to conductive accessible parts that are not grounded. A level of 8 kV for air discharge to all accessible parts. Test Methods IEC 801-2, Test Level: IEC 601-1-2

EMI Susceptibility:

The system shall be immune from levels of 1 v/m for the frequency range of 26 mHz to 1 gHz (IEC 801-3)

EMI Generation Limits:

System shall comply with the requirements of CISPR 11 for conducted and radiated emission

Input Line Protection:

Surge, fast transient/burst, lightning, IEC 801-4, IEC 801-5

### 7.3.5.4 Storage Environment

Temperature Range: -25° C. to +60° C.

Humidity: 0 to 95% RH (non-condensing) - not packaged for outdoor storage.

### 7.3.5.5 Mechanical Specifications

C-arm Rotation: +195° to 0° to -150° with detents at 0°, ±45°, ±90°, ±135° and +180°.

Rotation Lock: Electromagnetic

Vertical Travel: 28 to 56 inches (71-142 cm) from surface of Bucky to floor at 0°

Alignment of Focal Spot, Compression Device and Image Receptor:
The focal spot of the x-ray tube shall be located such that the ray falling on the edge of the image receptor closest to the chest wall is perpendicular to the image receptor. The system shall allow the plane formed by the focal spot and the chest wall of the device shall be perpendicular to that ray, and motion of the compression device shall provide essentially parallel compression of the breast with respect to the plane of the image receptor. The compression paddle and x-ray tube shall be adjustable, chest wall to nipple, to provide for this alignment requirement.

Source to Image Distance
65 cm (measured from nominal position of film in Bucky to the large focal spot.

Compression

A. Force
   a. Manual Compression: shall be limited to 65 lb. ±7 lb. maximum
   b. Motorized Compression:
      shall function in two user selectable operating modes
      (1) Pre-compression: provides compression in a range of 15-30lb., user-selected
      (2) Full compression: provides compression in a range of 20-40 lb., user selected

Note: motorized compression must be limited to 40 lb. in either mode.

B. Control: C-arm pushbuttons or 2 position footswitch

C. Compression Release: Motorized, initiated by pushbutton controls on C-arm and on operator panel. Automatic release enabled by software to release at end of exposure, unless inhibited by presence of localization paddle.

D. Release Distance: Automatic release shall move the compression device a distance of 15 cm., although in mag mode, this distance may be less.

E. Backdrive: After compression applied, backdrive of device shall not exceed 1.5 mm in either motorized or manual modes between -90°, 0°, and +90° C-arm positions, and no greater than 3 mm in any C-arm position outside that range.

F. Failure Mode: In the event of a power failure, there will be means for release of compression

G. Movement Interlock: Vertical C-arm drive and C-arm rotation will be disabled if there is approximately 10 lb. or more of compression force.

H. Compression Force Display:
Located on upper cover of compression device in combination with compression thickness and AEC detector position.

I. Compression Force Display Accuracy:
±3 lb. from 10 lb. to 35 lb. (±13.35 N from 44.5 N to 155.75 N); ±5 lb. Above 35 lb. (±22.25 N above 155.75 N);

J. Compression Thickness Measurement and Display:
Thickness shall be measured between 0 and 15 cm above the image receptor and displayed. The display shall be compensated for the type of image receptor installed. Display will be in 0.1 cm increments on compression device cover and on user interface screen.

K. Compression Thickness Accuracy:
±0.5 cm. at thickness between 0.5 and 10 cm.
±0.8 cm. at thickness between 0.5 and 10 cm.

L. Compression Paddles: the compression paddles will be transparent and marked with the location of the AEC sensor positions. The composition shall be either polycarbonate or PETg. The sensor position marking shall not be detectable on film when imaged with 1 cm of acrylic attenuator at 22 kVp to an optical density of 1.2 OD. The paddle attenuation shall be less than 15% (reduction OF mR/mAs) AT 25 kVp. The paddles will be designed to provide a parallel plane to the image receptor under 40 lb. Of compression force. The paddles will be adjustable to provide the focal spot, compression device and image receptor alignment requirement expressed previously.

Magnification — the magnification table will be constructed as a tower to provide rigidity. Alternatively, it will be a platform suspended from hangers on the C-arm.

A. Magnification Factor: 1.8x for objects 22.5 mm above the magnification stand breast support surface (the breast support surface will be at approximately 1.7x)

B. Material of Breast Support Surface: Transparent polycarbonate or carbon fiber composite.

C. Size of Breast Support Surface: 15 cm wide x 12 cm deep for table construction, or 18x24 cm for alternate construction.

### 7.3.5.6 Image Receptor Support Device

It will contain sensors for accessory detection. It will also provide space for the existing 3 cell AEC detector moveable to 7 positions at 1.7 cm. increments. The image receptor support device shall limit the x-ray transmission to no more than 0.1 mR for the maximum technique exposure to comply with 21 CFR, section 1020.31 and shall meet the 1 μGy per exposure as defined by IEC 601-1-3. Section 29.207.2.

### 7.3.5.7 X-ray Source Insert Specifications

| | |
|---|---|
| X-ray Tube: | Varian model B113/B115<br>Toshiba model E7290AX |
| Focal Spot Size: | Large 0.3 mm, Small 0.1 mm, nominal NEMA/IEC; the focal spot will be measured at a reference angle defined at 6° from the perpendicular, or chestwall, ray. The tube will be tilted 6° with a target angle of 16° to result in a total target angle to image plane angle of 22°. This reference angle is then the actual central ray of the x-ray tube. This must provide a system resolution of equal to or greater than 13 lp/mm in the width dimension and 11 lp/mm in the length dimension as measured per the ACR/CDC protocol. |
| Tube Voltage: | 22 kVp to 39 kVp maximum |
| Tube Current: | Large Focus - 80 mA between 22 and 28 kVp<br>Small Focus - 28 mA between 25 and 28 kVp<br>Operating speed of 3400 rpm (standard speed) |

Thermal Characteristics:

A. Anode Heat Storage : 210 kJ (300 kHU)

B. Maximum Anode Heat Dissipation Rate:
525 W (740 HU/s)

C. Housing Heat Storage Capacity:
610 kJ (860 kHU) min.

D. Maximum Housing Heat Dissipation Rate:
72 W (6 kHU/min) without air-circulator, 300 W (25 kHU/min) with air cooling

| | |
|---|---|
| Anode Rotation: | 50/60 Hz., 3000/3600 rpm |
| Anode Angle: | The x-ray tube will have a bi-angle anode with the large focal spot on a 10° angle. The tube will be tilted at a 6° angle to provide a 22° anode to film plane angle for the large and 16° anode to film plane angle for the small. This provides film of 24x30 cm for the large and 18x24 cm. for the small (magnification). |
| Anode Material: | Molybdenum |

X-ray window: Beryllium, 0.8 mm thickness maximum

X-ray Tube Housing and Tube Head Cover

Continuous Heat Dissipation:
300 watts

Maximum Temperature of the
Tube Housing Surface: 55° C.

Maximum Temperature of the
Tube Head Cover Surface: 41° C.

Over Temperature
Protection Sensor: Internally provided in series with stator common

Safety Class: IEC 601-2-28

### 7.3.5.9 X-ray Beam Filtration

Inherent Filtration: 0.0 mm Al equivalent

Added Filtration: 30 microns Molybdenum foil, or
25 microns Rhodium foil

Beam Quality: At a given kilovoltage, the measured HVL for Mo/Mo operation with the compression paddle in the x-ray beam will be equal to or greater than the value of kVp/100+0.03 in units of mm of aluminum but less than the value of kVp/100+0.12 in units of mm of aluminum. For Mo/Rh, min>kVp/100+0.03, Max<kVp/100+0.19.

Radiation Output: The radiation output through the compression paddle at the entrance surface of the breast (4.5 cm above the breast support, 4 cm from the chest wall) for the Mo/Mo target/filter, large focal spot combination operating at 28 kV shall be equal to or greater than 800 mR/second for at least 3 seconds.

### 7.3.5.10 X-ray Collimation:

The system shall detect the attached image receptor and automatically adjust the field size to limit the beam to 18x24 or 23x30 for large spot only. An aperture detect system will be used to insure that the correct aperture is used with the selected Image Receptor. Additional collimation will be provided by fixed apertures.

### 7.3.5.11 Light Field Indication

Light Field to X-ray Field Congruency:

Must be within 1% of the SID (0.65 cm) at all edges of the defined x-ray field. (21 CFR states that the light field to x-ray field misalignment be no greater than 2% of the SID for either the length or width which means our design criteria is 1% for each edge, or a total of 2% for length or width edges) Comply with IEC 601-1-3 pg. 51, 94 edition.

Light Field Lamp:

The lamp will be activated for a period of 30 seconds by switches located in the C-arm, whenever the compression down motor is activated. The lamp will be extinguished whenever the x-ray exposure is initiated. A shatter shield will be provided.

Light Field Illuminance:

The light localizer shall have a minimum illuminance of 160 lux and meet all of the requirements of 21 CFR, subchapter J, section 1020.31. The voltage at the lamp will be the least amount to assure 160 lux at low line conditions and there will be a surgistor in series with the lamp. These two elements will extend the life of the lamp considerable. The lamp will be surrounded by a shatter shield. The lamp will be adjustable to provide alignment of the light field to x-ray field.

### 7.3.5.12 High Voltage Generator

| | |
|---|---|
| Output Rating: | 2.4 kilowatt (70 mA at 34 kV) isowatt |
| Ripple: | Typically no greater than 2% with a maximum of 4% at lower output loads (less than 2.4 kW) and at low line voltages. |
| Topology: | Pulse width modulated high frequency, active servo controlled. |
| Duty Cycle: | 5 seconds on, 30 seconds off (1:7)<br>Note: this specification is for the thermal conditions of the high voltage generator. The actual operating duty cycle will be determined by calculation of the x-ray tube loading characteristics. This will permit exposures for stereotactic procedures to be made in as short of a time cycle as permitted by the tube loading. Thermal equilibrium testing will be done at technique factors of 200 mAs, 28 kV, at a rate of 1 exposure every 90 seconds. |

### 7.3.5.13 kV/mA Range

| kV | Large | Small |
|---|---|---|
| 22-24 | 80 | 24 |
| 25-28 | 80 | 28 |
| 29-34 | 70 | 24 |
| 35 | 60 | 20 |

Note: this is the minimum profile.

### 7.3.5.14 mAs Range

The M-IIIe will employ an integrating mAs timer for use as the manual timing as well as the back up timer. There will be an additional hardware safety timer employed to limit the maximum exposure time to 6 seconds.

| | |
|---|---|
| Manual mAs Range: | 3.0 through 400 mAs in 55 increments as follows: 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 12.0, 14.0, 16.0, 18.0, 20.0, 22.0, 24.0, 26.0, 28.0, 30.0, 32.5, 35.0, 37.5, 40.0, 42.5, 45.0, 47.5, 50.0, 55.0, 60.0, 65.0, 70.0, 75.0, 80.0, 85.0, 90.0, 95.0, 100.0, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200, 220, 240, 260, 280, 300, 325, 350, 375, 400 mAs. |

### 7.3.5.15 Accuracy, Reproducibility and Linearity

| | |
|---|---|
| Reproducibility: | 0.05 coefficient of variation for 10 consecutive exposures (21 CFR) Internal specification 0.04. |
| Linearity: | (radiation output versus selected mAs) 0.10 for adjacent mAs selections per the following (X1-X2)=to or less than 0.10(X1+X2) where X1 and X2 are average mR/mAs values for consecutive exposures (21CFR) Internal specification 0.09 |
| Accuracy: | kVp - the actual value will not differ by more than 1 kV from the indicated value. The difference between 2 actual kV stations will be in compliance with the difference of the indicated values.<br>mAs: ±5% from indicated<br>Post-mAs: ±5% from actual |

### 7.3.5.16 Image Receptors

The image receptor support device will be designed to accept the four standard image receptors, and the optional receptors listed below, which will be inserted from the front of the C-arm.

Standard items include:

A. 18x24 cm cassette holder
B. 24x30 cm cassette holder
C. 18x24 cm Bucky with linear lead strip grid
D. 24x30 cm Bucky with linear lead strip grid

Optional Items include:

A. HTC Bucky with air-interspaced cross-grid
B. StereoLoc II (film or DSM capable)
C. Digital Spot Mammography
D. Magnification Table

### 7.3.5.17 Automatic Exposure Control (AEC)

AEC Detector

The active sensing area will be 3 square centimeters, derived from three 1 cm square sensors.

AEC Detector Positioning

The detector will be able to be positioned in 7 locations, centered laterally in the image receptor support device. Position #1 will be located 1 cm from the chest wall, with positions 3, 5, and 7 in 3.4 cm. increments from position #1.

The AEC position indicators will be 7 LEDs which indicate the detented positions. The position indicators will be located on the upper compression device cover.

AEC kVp and Thickness Tracking

The AEC system shall have compensation for kVp between 22 kVp and 35 kVp, as well as compensation for breast thickness tracking including different breast compositions. Tracking will include film reciprocity failure compensation. The optical density shall be within 0.15 O.D. from the mean Optical Density value at any point within the clinically defined range of kVps for breast thicknesses between 2 cm and 6 cm of breast tissue equivalent material.

Reproducibility

See section 7.3.5.15.

Exposure Termination

The system shall determine if the exposure will reach "Back-up Time" and if so, will terminate the x-ray exposure within one of the following limits.

A. 50 milliseconds
B. 4 mAs
C. with an entrance exposure to the ACR Accreditation Phantom of less than 50 mR.

Indication will be made to the operator, and a manual reset will be required to continue the exam.

Density Range

There will be 11 density adjustment steps between -5 and +5 with a difference of approximately 10% in mAs from adjacent steps.

Post-mAs Display

There will be a display of the post-exposure mAs. The accuracy of the mAs displayed will be within 5% of the actual mAs. The display will hold until the initiation of the next exposure.

Modes of Operation

A. Manual: In this mode, the kV and mAs are both selectable.

B. Auto-Time: In this mode, the kV is the only factor selectable. The exposure is then terminated at a mAs value as determined by the AEC system microprocessor to yield an optical density to which the unit has been calibrated. A post-mAs readout indicates the mAs value at the end of the exposure and remains displayed until the initiation of the next exposure. This mode is valid for use with either the molybdenum or rhodium filter selected. The exposure may be modified up to ±50% by incrementing the DENSITY function. If determination is made that the exposure will exceed the Back-up Time, the exposure will be terminated in less than one of following limits: (a) 50 ms, (b) 4 mAs, or (c) with an entrance exposure to the ACR accreditation phantom of less than 50 mR, and indicate the termination to the operator.

C. Auto-kV: When this mode and the moly filter are selected, the kV will default to 25 kV as determined during default settings upon installation. The unit will be set to default to 25 kV at the factory. If the Rhodium filter is selected, the kV will be limited to 28-32 kV. The kV will default to 28 kV and the mA will be set to 70 mA. Normally there is no requirement to make any selection of technique in this mode. Upon exposure initiation, the AEC signal is sampled and the kV is modulated upward to a maximum of 28 kV if the moly filter is selected, or 32 kV if the Rhodium filter is selected, if determined necessary to provide an exposure within selected window of approximately 80 mAs, 120 mAs, or 160 mAs, as selected by the user. After the kV is modulated (approximately 50 msec into the exposure) the Auto-Time function completes the exposure. The post-kV and post-mAs are then displayed.

D. Auto- Filter: This mode provides fully automatic operation of all technique factors. The kV will initially default to 25 kV. The available range for the Auto-Filter mode is 25-32 kV. The exposure is initiated and sampled to determine if the kV needs to be modulated upward to provide an exposure within the 160 mAs window. When determined by the auto-filter algorithm, the exposure will be momentarily interrupted and the rhodium filter will be switched in. After the kV or kV/filter has been selected, the Auto-Time function completes the exposure. The final kV, post-mAs and filter will be indicated after the completion of the exposure. The mA is set to 70 mA for this mode.

## 7.4 Summary of Non-Clinical Testing

### 7.4.1 Overview of Performance Evaluations

To assess and provide measurement data on the mammographic imaging performance of the M-IIIe unit, a series of bench tests was developed and performed. The bench tests used the geometry and components of the M-IIIe system to (1) obtain system resolution measurements, (2) to provide images of standard mammographic quality assurance phantoms, (3) to evaluate tracking performance of the Automatic Exposure Control system, and (4) to evaluate performance in stereotactic localization. The tests and the results are summarized in this section.

### 7.4.2 System Resolution Tests

#### 7.4.2.1 Focal Spot Measurement

A. Measurement Method:
   1 degree Star Pattern
   25 kVp
   8 mAs large/2 mAs small
   Kodak Min R E Screen and Film
   90 second developing -- Kodak chemistry

B. Pass Criteria (NEMA method):

   Large Focal Spot (nominal 0.3 x 0.3 mm) maximum dimensions = 0.45 W x 0.65 L
   Small Focal Spot (nominal 0.1 x 0.1 mm) maximum dimensions = 0.15 W x 0.15 L

C. Results:

Large Focal Spot:

| | Test 1 | Test 2 |
|---|---|---|
| Width= | 0.43 | 0.43 |
| Length= | 0.48 | 0.49 |

Small Focal Spot:

| | Test 1 | Test 2 |
|---|---|---|
| Width= | 0.09 | 0.09 |
| Length= | 0.12 | 0.12 |

7.4.2.2 Line Pair Evaluation

A. Measurement Method

Nuclear Associates 5-20 lp/mm Line Pair Phantom (catalog number 07-555-EY) positioned 4.5 cm. above the top surface of a Lorad moving linear grid bucky device.
23 kVp Large FS/25 kVp Small FS
8 mAs large FS/2 mAs small FS
Kodak Min R E Screen and Film
90 second developing -- Kodak chemistry

B. Pass Criteria (ACR):

Parallel - 13 lp/mm
Perpendicular - 11 lp/mm

C. Results

Large Focal Spot:

| | Film 1 | Film 2 |
|---|---|---|
| Parallel = | 15 lp/mm | 15 lp/mm |
| Perpendicular= | 12 lp/mm | 13 lp/mm |

Small Focal Spot:

| | Film 3 | Film 4 |
|---|---|---|
| Parallel = | 16 lp/mm | 16 lp/mm |
| Perpendicular= | 13 lp/mm | 13 lp/mm |

7.4.3 Object Phantom Tests

Tests were performed using a standard anthropomorphic breast phantom. The RMI-156 phantom, which is recognized by the American College of Radiologists, as well as the regulations implementing the Mammography Quality Standards Act, and used in the certification process for mammography units, was used.

The phantom was imaged following normal clinical procedures to yield a film with an average optical density of 1.5. To provide a true indication of imaging performance, the mean glandular dose for the phantom images was evaluated, to ensure that the imaging performance was obtained at an absorbed dose level within the range acceptable for mammography.

The phantom images were scored according to standard ACR procedure, using three readers for each of two phantom films readers. The results are averaged summarized below.

| Object Group | ACR/MQSA Minimum | Phantom Film 1 | Phantom Film 2 |
|---|---|---|---|
| Fibers | 4 | 5.5 | 5.5 |
| Specks | 3 | 3.5 | 3.5 |
| Masses | 3 | 4 | 4 |
| Score | 10 | 13 | 13 |

| Mean Glandular Dose Limit for Screening Mammography Image (ACR) | MGD Measured for Phantom Film 1 | MGD Measured for Phantom Film 2 |
|---|---|---|
| 3 mGy | 1.84 mGy | 1.84 mGy |

| Parameter | Phantom Film 1 | Phantom Film 2 |
|---|---|---|
| Optical Density | 1.39 | 1.41 |
| Contrast Diff. Ratio (Avg. density - contrast disk)* | 0.42 | 0.44 |

* ACR Requirement = 0.40 approximate

7.4.4 AEC tracking

A. Test Method

Obtain automatically timed exposures using breast equivalent phantom materials from 2 to 8 cm at appropriate kV settings. Evaluate consistency of the resulting exposures in terms of optical density.

B. Test Materials

2-8 cm of BR-12 (45:55) breast equivalent phantom material.
Kodak Min R E film in Min R 2 cassette
Film Processing - Kodak chemistry, 90 second cycle.

C. Pass Criteria

Optical density of any film to be within ±0.15 of the average OD for all the test images

D. Results

| Average Optical Density | Minimum Optical Density | Maximum Optical Density |
|---|---|---|
| 1.27 | 1.17 | 1.36 |

The results for Automatic Exposure Control Tracking meet the specification.

7.4.5 Stereotactic evaluation

To evaluate the M-IIIE in terms of performing as a host mammography unit for an add-on stereotactic localization device, a prototype M-IIIE was fitted with a Lorad StereoLoc II device. The StereoLoc II device was tested first using a Lorad DSM digital imaging system as the imaging medium and targetting system, and then reconfigured to use film for imaging and targetting, and the performance tests repeated. The tests results supported compatibility with stereotactic procedures suing the StereoLoc II device with either film or DSM digital imaging.

7.4.5.1 Needle Positioning and Targetting Test

In this test, the positioning controls of the StereoLoc II device are calibrated and used to position a simulated lesion 1mm in diameter to a known 3-dimensional position (X=10mm, Y= 20mm and Z=30mm). Stereotactic images are then obtained and the simulated lesion is localized using the StereoLoc system controls. The localized X, Y and Z values are compared to the originally set X, Y and Z positions as an evaluation of accuracy of localization. This test confirms that the system is capable of providing accurate readings with the geometry of the M-III E host mammography unit.

A. StereoTactic Localization Results with StereoLoc II - DSM Equipped (512 mode)

| Set Position | Localized Results | Error |
|---|---|---|
| X=10 | X=10.1 | 0.1 |
| Y=20 | Y=20 | 0.0 |
| Z=30 | Z=30.6 | 0.6 |

Cumulative Error = sqr($Xerr^2$+$Yerr^2$+$Zerr^2$)=0.6
Specified Accuracy ±1 mm
Results meet specification.

B. StereoTactic Localization Results with StereoLoc II - DSM Equipped (1024 mode)

| Set Position | Localized Results | Error |
|---|---|---|
| X=10 | X=10.1 | 0.1 |
| Y=20 | Y=20 | 0.0 |
| Z=30 | Z=30.6 | 0.6 |

Cumulative Error = sqr($Xerr^2$+$Yerr^2$+$Zerr^2$)=0.6
Specified Accuracy ±1 mm
Results meet specification.

C. StereoTactic Localization Results with StereoLoc II- Film Equipped -

| Set Position | Localized Results | Error |
|---|---|---|
| X=10 | X= 10.1 | 0.1 |
| Y=20 | Y= 20.6 | 0.6 |
| Z=30 | Z= 29.7 | 0.3 |

Cumulative Error = sqr($Xerr^2$+$Yerr^2$+$Zerr^2$)= 0.68
Specified Accuracy ±1 mm Results meet specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1997

Philip Juhas
Regulatory Affairs Director
LORAD® Corporation
36 Apple Ridge Road
Danbury, CT 06810

Re: K973631
LORAD Model M-III (Mammographic X-Ray)
Dated: December 8, 1997
Received: December 11, 1997
Regulatory Class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Juhas:

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 requirement, 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/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin

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): K973631

Device Name: LORAD M-III ELITE (M-IIIE)

Indications For Use:

Screening and diagnostic mammography, including magnification studies, special views, spot compression views, as well as images used by a physician in preparing for a biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973631

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)