OCT 2 7 2011

K111434

**Traditional 510(k) Summary**

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

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|---|---|
| Submitter Information | Giotto USA, LLC<br>7324 Greenbriar Circle<br>Wichita, KS 67226 |
| Official Correspondent | Mr Robert Rusk<br>President<br>Giotto USA, LLC<br>Phone: 316-393-5966<br>E-mail: bobr@giottousa.com |
| Date: | May 19, 2011 |

807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Giotto Image 3D<br>Giotto Image 3D-L |
| Common Name | Full field digital mammography unit with amorphous Selenium detector |
| Device Classification Name | Full-Field Digital Mammography System |
| Product Code | MUE |
| Device Classification No.: | Part 892.1715 |
| Regulatory Status | Class II |

807.92(a)(3)
Predicate Devices

GE Healthcare Senographe Essential Digital Mammography System

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|---|---|
| PMA Number | P990066 |
| Giotto Image<br>510(k) Number | K012953 |

807.92 (a)(4)
Device Description

GIOTTO IMAGE-3DL Full field digital mammography unit with amorphous Selenium detector 24x30.

Versatile unit conceived for screening, but ideal for diagnostic. Very low x-ray dose emission, automatic and fast 3D movements of the circular arm, isocentric rotation, pre-arranged for stereotactic biopsy. x-ray tube with W/Re double track bi-angular anode 10°/16°, 0.1/0.3 mm focal spot, High Frequency/High Power 8 kW generator, Ag/Rh filters with automatic and manual insertion. Double digital display showing rotation and tilting angles of the circular gantry, compression force and compressed thickness.

The system includes:

- Giotto IMAGE mammography unit with motorized tube rotation ± 24° for stereotactic biopsy.
- Amorphous Selenium detector 24 x 30 cm
- MAW (Management & Acquisition Workstation) ) with 21" LCD 2Mpixel monitor, dedicated computer for images acquisition/processing. DVD/CD professional burner.
- Raffaello® (AWS) software: Graphic User Interface for visualization and processing of digital mammographic images. DICOM 3 interface.

The Giotto Image 3DL consists of gantry with a vertical column, a circular support for the x-ray tube, and compression mechanism, and an x-ray generator all of which are very similar to the Giotto Image analog mammography system previously cleared under 510(k) K012953. It incorporates an 24 X 30 amorphous selenium detector that directly captures x-rays and converts the them into electronic signal from which the images are constructed. The images are displayed on am monitor for review by the operator.

The x-ray tube used is a Varian with tungsten anode and Ag/Rh filters. The gantry can be positioned automatically via motorized movement in 3 dimensions.

Images are produced with proprietary acquisition and processing algorithms and displayed at an operator acquisition where the operator may enter patient data (or it is received from a DICOM worklist). The images are transmitted from the acquisition station to a workstation for interpretation.

807.92(a)(5)
Intended Use(s)

The intended use of the Giotto Image 3D is to pro duce digital images suitable for screening and diagnostic examination of the breast for detection of breast cancer.

The intended use of the Giotto Image 3D-L is to prod uce digital images suitable for screening and diagnostic examination of the breast for detection of breast cancer.

807.92(a)(6)
Technological Characteristics

The Giotto 3D and 3D-L systems employ the same fundamental technological characteristics as their predicate devices. The X-ray technology for both the 3D and 3D-L systems is substantially equivalent to the Giotto Image cleared by FDA via K012953. The Giotto 3D and 3D-L incorporate full-field flat panel detector similar to that used by the GE Senographe Essential.

- Clinical uses for which the Giotto I mage 3D and 3D-L are designed, are equivalent to those cleared for Giotto Image and GE's Senographe.
- Giotto Image 3D and 3D-L are designed to meet the IEC60601-1, IEC 60601-2-45, and IEC60601-2-32 safety requirements.
- The Giotto Im age 3D a nd 3D-L use a differe nt technology for converting x-rays to electric signal than GE's Senographe. Th e Giotto detector us es a direct energy conversion technology (from x-ray photons to el ectrical charges) while the GE detector uses an indirect energy conversion technol ogy (from x-ray photons to light photons and from light photons to electrical charges) Howeve r, they are Substantially Equivalent with respect to safety and effectiveness.
- The Giotto Image (analog) is a sc reen film system and the Giotto Im age 3D and Giotto Image 3DL and the GE Senographe Essential incorporate a full field flat Panel detector.

807.92(b)(1)
Summary of Non-Clinical Tests

The devices have been evaluated for as electrical, electromagnetic, radiation, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-3
- IEC 60601-1-4
- IEC 60601-1-6
- IEC 60601-1-8
- IEC 60601-2-32
- IEC 6060 1-2-45
- IEC 62304
- ISO 14971

807.92(b)(2)
Summary of Clinical Tests

No clinical tests were performed, but radiological examination of images was performed. Image sets and associated information from screening and diagnostic examinations of six patients with BI-RADS® Assessment Categories of 1or 2. The image sets consist of four images: craniocaudal (CC) and mediolateral oblique (MLO) views of each breast. Three of these image sets also contain diagnostic images (spot and/or magnification). At least two sets of images are from patients having fatty breasts and two from patients having dense breasts, as described in the BI-RADS ®Atlas.

The images were selected by IMS and Giotto USA, LLC staff and radiologists at various mammography facilities in Europe as representative of typical mammography examinations performed with the Giotto Image 3DL. Expert radiologists assessed the image sets and provided an opinion as to whether or not the images in each case are of "sufficiently acceptable quality for mammographic usage to allow determination of substantial equivalence" to a mammography device previously approved or cleared by FDA.

807.92(b)(3)
Conclusion

The Giotto 3D and 3D-L are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 27 2011

Giotto USA, LLC
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The Anson Group
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INDIANAPOLIS IN 46268

Re: K111434
Trade/Device Name: Giotto Image 3D, Giotto Image 3D-L
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: September 9, 2011
Received: September 12, 2011

Dear Mr. Mooney:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): K111434

Device Name: Giotto Image 3D, Giotto Image 3D-L

Indications for Use

The intended use of the Giotto Image 3D is to produce digital images suitable for screening and diagnostic examination of the breast for detection of breast cancer.

The intended use of the Giotto Image 3D-L is to produce digital images suitable for screening and diagnostic examination of the breast for detection of breast cancer.

Prescription Use YES AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111434