NOV 3 0 2001

510(k) Summary

K012953
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1. Submitter Information

1.1. Submitter:
MEDX Incorporated
3456 N. Ridge Ave., #100
Arlington Heights
IL 60004
Phone: (847) 463-2020
Fax. (847) 463-2019

1.2. Manufacturing Facility:
Internazionale Medico Scientifica S.r.l.
Via Sagittario, 5 – 40044 Pontecchio Marconi
Bologna, Italy

1.3. Contact:
Floyd Rowan

1.4. Date: August 30, 2001

2. Device Name

2.1.	***Classification Name:***	System Mammographic
	Classification Number:	90IZH
2.2.	***Trade/Proprietary Name:***	Giotto Image
2.3.	***Predicate Device:***	Giotto HT (DC K973856)

3. Device Description

3.1. ***Function***

The Giotto Image is a conventional film-screen x-ray mammographic device. This device is designed to generate a high resolution image of the breast on film using an x-ray source designed specifically for mammography. It incorporates a state-of-the-art microprocessor controlled high frequency single phase x-ray generator and automatic exposure control, molybdenum rotating anode x-ray tube with 0.3 and 0.1 mm focal spots, gantry, compression device and film holder. The unique open design of the Giotto Image allows positioning of the patient with the operator facing the patient. This face-to-face positioning allows the operator to carefully center the breast and compress it quickly and efficiently. Optional accessories allow both prone and seated breast needle biopsy.

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3.2. Scientific Concepts:

X-ray imaging began in the late nineteenth century with the discovery of x-rays by William Conrad Roentgen. X-ray imaging of the human anatomy, including the breast, began immediately after this discovery. The danger of x-ray exposure, tissue damage caused by ionizing radiation, was quickly recognized and today is known to be a major limitation of x-ray imaging. It was not until the 1980's that the unique requirements of x-ray mammography for the detection of non-palpable lesions were realized, resulting in the development of specialized x-ray mammographic units. These devices incorporate special x-ray tubes and low ripple x-ray generators producing much lower energy x-rays than conventional x-ray systems. These low energy x-rays allow penetration of the breast tissue while at the same time producing sufficient contrast on the film to detect non-palpable breast lesions. Film screen systems for mammography have been optimized to produce the high resolution images required by mammography while at the same time minimizing dose to the patient.

3.3. Physical and Performance Characteristics:

Mammography has been demonstrated to be the best imaging choice for screening of women for breast cancer by many studies and is currently recommended as a routine procedure for women over 50 years of age.
The FDA has introduced the MQSA program to ensure consistent quality among mammography providers. The MQSA has adopted the accreditation program administered by the American College of Radiology (ACR). This program sets forth requirements for mammography equipment including image resolution, contrast resolution, dose, kV accuracy, etc. The Giotto Image has been designed to meet or exceed all the ACR requirements.

4. Device Intended Use

4.1. The intended uses of the Giotto Image are identical to the intended uses of the Giotto HT predicate device (Premarket notification K973856).

5. Device Technological Characteristics

5.1. The characteristics of the Giotto Image system compare substantially with the Giotto HT, in both materials used, technology applied, and functional methodology. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category, and performs as well as the predicate Giotto HT.

5.2. The components of the Giotto Image that come in direct contact with the patient (paddles, supports, holders, Bucky) are of the same materials as the Giotto HT predicate device (Premarket notification K973856).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2001

Mr. Floyd R. Rowan
Executive Vice President
Medx, Inc.
3456 N. Ridge Ave., #100
ARLINGTON HEIGHTS IL 60004

Re: K012953
Trade/Device Name: Giotto Image
Mammographic x-ray system
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: 90 IZH
Dated: August 30, 2001
Received: September 4, 2001

Dear Mr. Rowan:

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.

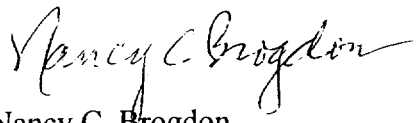
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012953

Device Name: Giotto Image X-ray Mammographic System

Indications For Use:

The Giotto Image X-ray Mammographic System is intended to provide film-screen X-ray imaging of the breast that can be imaged on a 18 x 24cm or 24 x 30cm film. With optional accessories the Giotto Image can also be used as the imaging device for stereotactic needle 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, and Radiological Devices
510(k) Number K012953

(Optional Format 3-10-98)

Prescription Use ✓