

**1. Submitter Information:**

1.1. Submitter:  
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NOV 21 1997

1.2. Manufacturing Facility:  
Internazionale Medico Scientifica S.r.l.  
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Bologna, Italy

1.3. Contact:  
Robert H. McCarthy

1.4. Date: September 29, 1997

**2. Device Name**

- 2.1. **Classification Name:** System Mammographic
- 2.1. **Classification Number:** 901ZH
- 2.2. **Trade/Proprietary Name:** Giotto HT
- 2.3. **Predicate Device:** Giotto HF (DC K901558)

**3. Device Description**

**3.1. Function**

The Giotto HT 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 HT 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.

## 510(k) Summary

Optional accessories allow both prone and seated breast needle biopsy.

### 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 the 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 HT has been designed to meet or exceed all the ACR requirements.

## 4. **Device Intended Use:**

- 4.1. The intended uses of the Giotto HT are identical to the intended uses of the Giotto HF predicate device (Premarket notification K901558)..

## 510(k) Summary

### 5. Device Technological Characteristics:

**5.1.** The characteristics of the Giotto HT system compare substantially with the Giotto HF, 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 HF.

#### **5.2. *Biocompatibility***

The components of the Giotto HT that come in direct contact with the patient (paddles, supports, holders, Bucky) are of the same materials as the the Giotto HF predicate device (Premarket notification K901558)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert H. McCarthy  
Vice President  
SITCO Incorporated  
25663 Hillview Court  
Mundelein, Illinois 60060

Re: K973856  
Giotto HT Mammographic System  
Dated: September 29, 1997  
Received: October 9, 1997  
Regulatory class: II  
21 CFR 892.1710/Procode: 90 IZH

NOV 21 1997

Dear Mr. McCarthy:

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, 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): K973856

Device Name: Giotto HT

Indications For Use:

The Giotto RT is intended to provide film-screen X-ray imaging of the breast and other soft-tissue organs that can be imaged on a 18 x 24cm or 24 x 30cm film. With optional accessories the Giotto HT 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)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*David A. Johnson*  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K973856