510(k) Summary

K062039

1. Submitter Information

SEP 11 2006

1.1. Submitter:
GIOTTO USA, LLC
1822 East 1st Street
Wichita, KS 67214
Phone: 316-393-5966
Fax. 316-263-4686

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

1.3. Contact:
Robert Rusk

1.4. Date: 17-Jul-06

2. Device Name

2.1. ***Classification Name:*** System Mammographic
Classification Number: 90IZH

2.2. ***Trade/Proprietary Name:*** BIOPSY DIGIT-AM

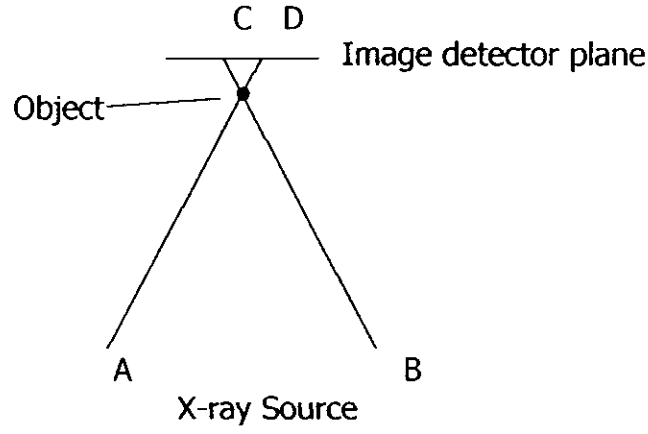
2.3. ***Predicate Device:*** BIOPSY DIGIT (DC K990192)

3. Device Description

3.1. ***Function***
The BIOPSY DIGIT-AM device uses two stereo images taken by a digital solid state camera to determine the location of a lesion in three dimensions. Once the coordinates of the lesion are determined by the BIOPSY DIGIT-AM they are used to position a needle holder such that when the physician inserts the needle or guide-wire, the tip will be precisely positioned at the pre-determined coordinates.

3.2. ***Scientific Concepts:***
The BIOPSY DIGIT-AM works on the same principle as human binocular vision. Two images of the same object are taken with the x-ray source in two different

positions. Objects between the source and film plane appear at a different location as the source is moved from position A to B as shown in the figure below. Since the geometry of the system is fixed and knew, given the apparent position of the object in the two views, shown as C and D in the figure, the true position of the object can be calculated.



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. Mammography, however, has been shown to have a high rate of false positive examinations.

Stereotactic needle localization has been shown to be a minimally invasive procedure for obtaining the tissue sample needed determining the lesion type for a positive mammography examination. The procedure removes much less tissue and produces much less scar tissue than conventional surgical biopsy.

4. Device Intended Use

4.1. The intended uses of the BIOPSY DIGIT-AM are identical to the intended uses of the BIOPSY DIGIT predicate device (Premarket notification K990192).

5. Device Technological Characteristics

5.1. The characteristics of the BIOPSY DIGIT-AM system compare substantially with the BIOPSY DIGIT, 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 BIOPSY DIGIT.

510(k) Summary K062039

5.2. The components of the BIOPSY DIGIT-AM that come in direct contact with the patient (paddles, supports, holders, digital camera) are of the same materials as the BIOPSY DIGIT predicate device (Premarket notification K990192).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Giotto USA
c/o Ms. Allison Scott
Consultant
The Anson Group, LLC
11460 N. Meridian St., Suite 150
CARMEL IN 46032

SEP 11 2006

Re: K062039
Trade/Device Name: Biopsy Digit-AM
Regulation Number: 21 CFR §892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: July 18, 2006
Received: July 19, 2006

Dear Ms. Scott:

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 (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 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 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 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062039

Device Name: Biopsy Digit-AM

Indications For Use:

The Biopsy Digit-AM is intended to be used for mammographic procedures requiring stereotactic guidance, such as fine needle aspiration, needle biopsy, and guide wire placement.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lieberman

(Division Sign-Off)
Division of Reproductive, Abd...
and Radiological Devices
510(k) Number K062039