3/12/99

510(k) Summary

K990192

1. Submitter Information:

1.1. Submitter:
SITCO Incorporated
3456 N. Ridge Ave. #100
Arlington Heights, IL 60004
Phone: (847) 463-2001
FAX: (847) 463-2011

1.2. Manufacturing Facility:
Internazionale Medico Scientifica S.r.l.
Via Pila, 1/8 – 40044 Pontecchio Marconi
Bologna, Italy

1.3. Contact:
Robert H. McCarthy

1.4. Date: December 31, 1998

2. Device Name

2.1.	***Classification Name:***	System Mammographic
	Classification Number:	901ZH
2.2.	***Trade/Proprietary Name:***	Biopsy Digit
2.3.	***Predicate Device:***	Fischer MammoVision (DC K923061)

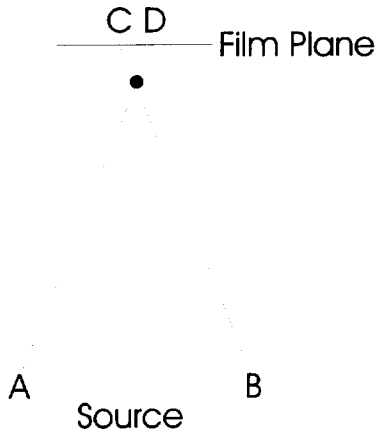
3. Device Description

3.1. Function

The Biopsy-Digit 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 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 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, 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 samples needed determining the lesion type for a positive mammography examination. The procedure removes much less tissue than and produces much less scar tissue than conventional surgical biopsy.

4. Device Intended Use:

4.1. The intended uses of the Biopsy Digit are mammographic procedures requiring stereotactic guidance, such as fine needle aspiration, needle biopsy and guide wire placement. The intended uses are identical to those of the predicate device.

5. Device Technological Characteristics:

5.1. The characteristics of the Biopsy-Digit system compare substantially with the Fischer Mammovision predicate device, 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 Mammovision.

5.2. Biocompatibility

The components of the Biopsy-Digit that come in direct contact with the patient (paddles, supports, holders, Digital camera) are of the same materials as the the Biopsy-M (Premarket notification K982049)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Robert H. McCarthy
Vice President
SITCO, Inc.
3456 N. Ridge Avenue #100
Arlington Heights, IL 60004

Re: K990192
Biopsy-Digit
Dated: December 31, 1998
Received: January 21, 1999
Regulatory class: II
21 CFR 892.1710/Procode: 90 IZH

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): K990192

Device Name: Biopsy-Digit

Indications For Use:

The intended uses of the Biopsy Digit are mammographic procedures requiring stereotactic guidance, such as fine needle aspiration, needle biopsy and guide wire placement.

(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 K990192

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)