K973496

Auto Suture* Minimally Invasive Breast Biopsy (MIBB**) System

IX. 510(k) Summary of Safety and Effectiveness

DEC - 1 1997

SUBMITTER:	United States Surgical Corporation 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Victor M. Clavelli
DATE PREPARED:	September 8, 1997
CLASSIFICATION NAME:	Biopsy Instrument
COMMON NAME:	Biopsy Needle
PROPRIETARY NAME:	Not Yet Determined
PREDICATE DEVICES:	Mammotome® (K970565)
DEVICE DESCRIPTION:	The MIBB** system is comprised of a biopsy needle probe, a probe driver and a control module vacuum source. The MIBB** system is a minimally invasive biopsy device designed to pierce, cut and collect tissue during a biopsy procedure.
INTENDED USE:	***The Auto Suture* MIBB** System has indication in incisional breast biopsy procedures for diagnostic purposes only and is not intended for therapeutic purposes.***
MATERIALS:	The AUTO SUTURE* MIBB** system is composed entirely of biosafe materials which have passed biocompatibility testing appropriate for their intended patient contact profile in accordance with ISO 10993-1.

* Trademark of United States Surgical Corporation

** Trademark name not yet determined

(revised)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 1997

Mr. Victor M. Clavelli
Sr. Associate, Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K973496
Trade Name: Auto Suture Minimally Invasive Breast Biopsy (MIBB) System
Regulatory Class: II
Product Code: KNW
Dated: September 9, 1997
Received: September 15, 1997

Dear Mr. Clavelli:

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 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) 594-4595. 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Auto Suture* Minimally Invasive Breast Biopsy (MIBB**) System

IV. Indications For Use:

510(k) Number (if known): K973496

Device Name: AUTO SUTURE* MIBB** System

Indications For Use:

The Auto Suture* MIBB** System has indication in incisional breast biopsy procedures for diagnostic purposes only and is not intended for therapeutic purposes.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973496

* Trademark of United States Surgical Corporation
** Trademark name not yet determined

(revised)