

Auto Suture* ABBI* System

K983296

SE 6-4-99

IX. 510(k) Summary of Safety and Effectiveness

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

CONTACT PERSON: Christopher A. Graham

DATE PREPARED: June 4, 1999

CLASSIFICATION NAME: Instrument, Biopsy

COMMON NAME: Instrument, Biopsy

PROPRIETARY NAME: Auto Suture* ABBI* System

PREDICATE DEVICES: Auto Suture* ABBI* System (K963825).

DEVICE DESCRIPTION: The Auto Suture* ABBI* System uses stereotactic mammography to target non-palpable breast abnormalities for biopsy. The system includes a disposable biopsy device, which uses a circular scalpel and electrocautery snare to excise a diagnostic sample for diagnosis.

INTENDED USE: To be used when stereotactically localized, large diameter, breast biopsies, identified by the placement of a needle localization wire, are desired for diagnostic sampling of a mammographic abnormality that is suspicious for malignant disease (i.e. usually BIRADS class 4 or 5). The ABBI* device is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of a histologic abnormality cannot be determined from its mammographic appearance. Therefore, the extent of removal of a mammographic abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled mammographic abnormality or the sampled tissue is not histologically benign, it is essential that the tissue margins be examined for completeness of removal.

The device is available in 5, 10, 15 and 20mm diameters. Device diameter should be matched to desired diameter of tissue sample for diagnosis.

Auto Suture* ABBI* System

MATERIALS: All component materials of the Auto Suture* ABBI* System are comprised of materials which are in accordance with ISO Standard # 10993-1.

CLINICAL SUMMARY: In a multi-centered, non-randomized, prospective study, 106 patients underwent breast biopsy procedures using the Auto Suture* ABBI* System to evaluate the device for use in the removal of mammographic abnormalities. The Auto Suture* ABBI* System was evaluated on the following endpoints:

- **Primary endpoint:** 106 of the 106 (100%) complete procedures were successful for a histological diagnosis. 85 patients (80.2%) had benign lesions and 21 patients (19.8%) had malignant lesions. Of the 21 patients with malignant lesions, 7 (33.3%) had negative margins, 11 (52.4%) had positive margins, and 3 (14.3%) were undetermined. Consistent with the standard of care for excisional biopsies, all patients with malignancies were treated with a therapeutic modality after the diagnostic ABBI* procedure.
- **Secondary endpoint:** 106 of the 106 (100%) procedures were successful, in terms of removing a mammographically visible abnormality that had been radiographically marked for the purpose of diagnosis. 102 of the 106 (96.2%) procedures were completely removed, as verified by the presence of the lesion in the specimen radiograph and by its absence in the patient's post-operative mammogram of the biopsy site.



JUN 4 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Christopher A. Graham
Senior Associate, Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K983296
Trade Name: Auto Suture ABBI System
Regulatory Class: II
Product Code: KNW
Dated: May 10, 1999
Received: May 12, 1999

Dear Mr. Graham:

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.

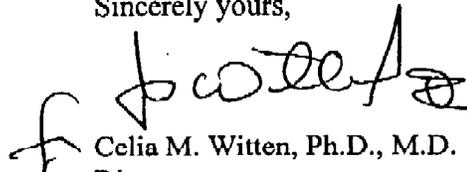
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Christopher A. Graham

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "M".

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* ABBI* System

IV. Indications For Use:

510(k) Number (if known): _____

Name: Auto Suture* ABBI* System

Indications For-Use:

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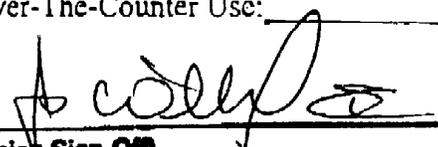
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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: X
(Per 21 CFR §801.109)

OR Over-The-Counter Use: _____


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

K983296