



K984157

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510(k) Summary

11/15/98

Mill Pond, Inc Contact Person: Gregory E. Sancoff
Trade or Proprietary Name: None available at this time
Common or Usual Name: Stainless steel suture wire and device for applying same
Classification Name: Suture, nonabsorbable, steel, monofilament and multifilament

Devices to Which Equivalence is Claimed

The subject device is substantially equivalent to the Lukens® Stainless Steel Surgical Suture, the U.S. Surgical Corporation Auto Suture® Powered Endoscopic GIA Stapler, and certain aspects of the 3M Maxi-Driver II Battery-Powered System.

Description of Subject Device

The subject device is a reuseable hand-held instrument that places stainless steel sutures in an open or minimally invasive surgical procedure. The suture material is supplied in a sterile disposable format that involves structures for dispensing the suture and for mounting this to the instrument. The device consists of a handle, a shaft, and a jaw at the end of the shaft. The jaw, which opens and closes via a manual lever on the handle, holds the tissue to be sutured. An electric switch also on the handle activates a battery-powered motor mechanism that drives the suture wire through the tissue.

The jaw is then used to grab both strands of wire near where they emanate from the tissue. A second electric switch on the handle activates another motor that rotates the jaw causing the wire ends to twist about themselves bringing the tissue together until the desired amount of tension is developed. Another manual lever on the handle is used to cut the wire. The device is now ready for the next suture.

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Intended Use of Subject Device

Surgical device to connect tissue.

Comparison of Technical Aspects

The subject device is a reuseable hand-held instrument that places stainless steel sutures in an open or minimally invasive surgical environment. The U.S. Surgical Corporation device is disposable and performs the same function except that it uses stainless steel staples that are driven into the tissue using compressed gas as a power source. The subject device uses battery-powered electric motors for the functions of moving the wire through the tissue and for twisting the wire ends together. The 3M Maxi-Driver II Battery Powered System is a reuseable hand-held instrument for machining bones that also uses an electric motor as a mechanical energy source. The 3M device and the subject device are both sterilizable. The entire U.S. Surgical Corporation device is disposable whereas only the suture material and its container and support tube are disposable with the subject device.

The staples of the U.S. Surgical Corporation device are made of small pieces of stainless steel wire that are pushed into the tissue and the ends are bent to keep the tissue in place. The subject device pushes stainless steel suture wire through tissue and twists the ends of the wire to form a continuous closed loop that holds the tissue together.

The wire material used for the subject device is 316L stainless steel which is the identical stainless steel used in the Lukcns and U. S. Surgical Corporation devices.

Sterilization guidelines of both the instrument and the disposable will be verified according to the referenced AAMI documents.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1999

Mr. Gregory E. Sancioff
President and Chief Executive Officer
Mill Pond, Inc.
One Stiles Road, Suite 104
Salem, New Hampshire 03079

Re: K984151
Trade Name: Stainless Steel Suture and Applier
Regulatory Class: II
Product Code: GAQ
Dated: February 19, 1999
Received: February 23, 1999

Dear Mr. Sancioff :

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 that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification will be announced in a future Federal Register notice. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Mill Pond, Inc. Stainless Steel Surgical Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure, and certain orthopedic procedures including cerclage and tendon repair.
2. This device may not be manufactured from any metal other than 316L stainless steel. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Mill Pond, Inc. Stainless Steel surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

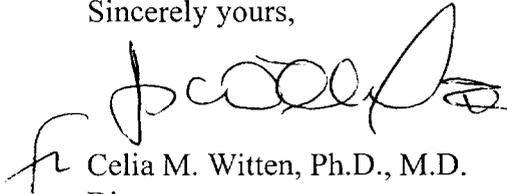
The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, 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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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

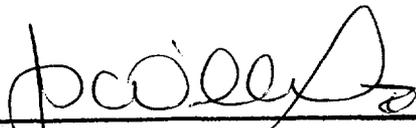
Enclosure

Statement of Indications for Use

INDICATIONS

Mill Pond, Inc. Stainless Steel Surgical Suture used with the Mill Pond, Inc. Suture has applications in gynecological, orthopedic, and general abdominal and thoracic endoscopic surgical wound closure procedures including creation of anastomoses and hernia repair.

PRESCRIPTION X



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

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