MAY 1 0 2004 K040602 Page 1/2

Design Standards Corporation

510(k) March 2004

510 (k) SUMMARY: Sureline™ Laparoscopic Clip Applier with Implantable Titanium Clips

(1) Design Standards Corporation
182 CEDA Rd.
Charlestown, NH 03603
(603) 826-7744

Contact Person: Michele Lucey
Date Summary Prepared: September 2, 2003

(2) Trade or Proprietary Name: Sureline™ Laparoscopic Clip Applier with Implantable Titanium Clips

Common Name: Laparoscopic Clip Applier with Implantable Titanium Clips

Classified Name: Implantable Clip (74FZP), 21 CFR 878.4300, Class II

(3) Predicates:

Vitalitec International
(k981645)
Microsurge Sureline
(964109)
United States Surgical Corporation
(K883081, K890941)
Ethicon Endosurgery (K920387)
Pilling Weck (K851251, K905837))

(4) Description of Device:

The Sureline™ Laparoscopic Clip Applier with implantable titanium clips is a disposable single patient use device fabricated from biocompatible stainless steels and biocompatible medical grade polymers. The product is also available as a reusable clip applier and disposable clip cartridge. The disposable clip applier and disposable clip cartridge contain 20 titanium clips. The clip cartridge is attached to the clip applier handle via

a lock/release mechanism, and inserted through a trocar to gain laparoscopic access. The clip cartridge jaws with the open clip in the jaws is placed around the vessel or other tubular structure. Actuation/compression of the clip applier handle/trigger drives a mechanism within the cartridge to close the cartridge jaws, thereby forming the clip securely around the vessel. Release/decompression of the clip applier handle/trigger allows the jaws of the cartridge to open and releases the clip from the cartridge jaws. The automatic feeding cartridge releases the next clip into the jaws for another application.

The cartridge is sized to fit through a 10 mm cannula. The overall shaft length of the cartridge plus the clip applier handle is approximately 33 mm, consistent with other endoscopic instruments.

(5) Intended Use:

The Sureline™ Laparoscopic Clip Applier with implantable titanium clips is intended for use during laparoscopic surgery to occlude a variety of vessels or other tubular structures.

(6) Technological Characteristics:

The Sureline™ Laparoscopic Clip Applier with implantable titanium clips has similar/same technological characteristics as the predicate devices in that they are comprised of similar design, materials, and are intended for use to clip vessels or tubular structures during laparoscopic surgery.

(7) Conclusion:

The new device has the same intended use and the same basic technology as the predicates identified in the premarket notification submission. The new device contains in some combination similar/same features, materials, and design as the predicates and does not pose any new questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2004

Ms. Michele Lucey
Director of Regulatory Affairs
and Quality Assurance
Design Standards Corporation
182 Ceda Road
P.O. Box 1620
Charlestown, New Hampshire 03603

Re: K040602
Trade/Device Name: Sureline™ Laparoscopic Clip Applier with Implantable Titanium Clips
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: March 1, 2004
Received: March 8, 2004

Dear Ms. Lucey:

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 (PMA), 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K040602

Device Name: Sureline™ Laparoscopic Clip Applier with Implantable Titanium Clips

Indications For Use:

The Sureline Laparoscopic Clip Applier with Implantable Titanium clips is intended for use in a variety of laparoscopic procedures to occlude tubular structures and blood vessels. The tissue being ligated should be consistent with the size of the clip.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040602

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

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

Concurrence of CORH, Office of Device Evaluation (ODE)