K121822

## 510(k) Summary

SEP 10 2012

510(K) Owner:

American Surgical Company, LLC
(formerly American Surgical Sponges, LLC and American Silk Sutures Inc.)
82 Sanderson Avenue
Lynn, MA 01902
781-592-7200
Owner/Operator Number: 10030544

Submitter:

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American Surgical Company
82 Sanderson Avenue
Lynn, MA 01902
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Contact:

Erik Piasio
Managing Director
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Manufacturer:

American Surgical Company, LLC
82 Sanderson Avenue, Suite 212
Lynn, MA 01902
781-592-7200
Registration Number: 1221144

Date Prepared: 8 June 2012

Trade name: Delicot Surgical Sponge

Common name: Neurosurgical Paddie or Sponge

Classification name: 21 CFR § 882.4700

Product Code(s): HBA (neurosurgical paddie)

Classification: Class II

Current Legally Marketed Device:

Ray-Cot, Uniqcot and Delicot Neurosurgical Sponges K902921

K121822

Policot Neurosurgical Sponge K862494

Summary Description of the Device:

The device is a non-adherent, strung, x-ray detectable surgical sponge that is sterile and disposable. The Delicot product line is made from lyocell, a manmade fiber derived from cellulose, better known under the brand name of Tencel - a type of rayon; it is supplied in various lengths and widths and has been marketed since 1990. The Delicot product line is one of three rayon-based sponges. The Delicot sponges are manufactured using Dupont Style 8623 consisting of 100% lyocell. Dupont has discontinued the manufacture of Style 8623. Dupont Style 8471 consisting of 58% polyester and 42% lyocell is our proposed replacement.

Intended Use:

The device is a neurosurgical pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

Indications for Use:

The device is a neurosurgical pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

Substantial Equivalence:

The modified Delicot Neurosurgical Sponges are equivalent to the previously cleared 510(k) (K902921 Sept. 18, 1990 and K862494 July 30, 1986) as these devices:

- have the same indications for use and intended use,
- use the same principle of operation,
- incorporate the same basic design,
- incorporate equivalent materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

In summary, the modification to the Delicot Neurosurgical Sponges described in this submission is substantially equivalent to the predicate device.

Biocompatibility Testing:

Biocompatibility testing included Cytotoxicity and was completed in accordance with FDA's Blue Book Guidance G95-1 ("Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' "). The results of the study demonstrate the lack of toxicity of the device and its biocompatibility for use as a neurosurgical sponge. The study was conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58.

Performance Standards:

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, American Surgical Company conducted comparability testing on the existing Delicot sponge and the Delicot sponge with the replacement material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

American Surgical Company, LLC
c/o Mr. Erik Piasio
82 Sanderson Avenue
Lynn, MA 01902

SEP 10 2012

Re: K121822
Trade/Device Name: Delicot Surgical Sponge
Regulation Number: 21 CFR 882.4700
Regulation Name: Neurosurgical Paddie
Regulatory Class: Class II
Product Code: HBA
Dated: August 13, 2012
Received: August 16, 2012

Dear Mr. Piasio:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 1.0 Indications for Use

510(k) Number (if known): K121822

Device Name: Delicot Neurosurgical Sponge

Indications for Use: The device is a neurosurgical pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices



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