K112598

2.0 510(k) Summary

JUN 2 0 2013

510(K) Owner: American Surgical Company, LLC
(formerly American Surgical Sponges, LLC and American Silk Sutures Inc)
82 Sanderson Avenue, Suite 212
Lynn, MA 01902
781-592-7200
Owner/Operator Number: 10030544

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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: 01 September 2011

Trade name: American Surgical Sponges (brand) Neurosurgical Sponges

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:

American Surgical Company
Special 510(k)

American Surgical Sponges (brand) Neurosurgical Sponges
K962807

Summary Description of the Device:

The device is a non-adherent, strung, x-ray detectable surgical sponge that is sterile and disposable. The American Surgical Sponges (brand) product line is made from cotton, polyester, or rayon in various sizes and shapes and has been first marketed since 1985. The current cleared product line includes the Telfa® Sponges, which are cotton surgical sponges covered on both sides with polyethylene terephthalate. The Telfa® Sponges provide additional stiffness to the neurosurgical sponges. The new proposed addition to the product line includes neurosurgical sponges (cotton, polyester, or rayon) covered on one side with a thin single layer of polytetrafluoroethylene (PTFE) to enhance the material stiffness and non-adherence properties while maintaining flexibility of the sponge. The polytetrafluoroethylene (PTFE) layer will be provided in a choice of three thicknesses, 0.001", 0.003" or 0.005". The sponges range in size from 6mm × 76mm to 25mm × 76mm.

Intended Use:

The device is intended to be used by trained physicians during neurosurgical procedures to protect neural tissues from drying, abrasion, or contamination and to absorb fluids.

Indications for Use:

The device is indicated for use by trained physicians during neurosurgical procedures to protect neural tissues from drying, abrasion, or contamination and to absorb fluids.

Substantial Equivalence:

The modified American Surgical Sponges (brand) Neurosurgical Sponges is equivalent to the previously cleared 510(k) (K962807, May 2, 1997) 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 American Surgical Sponges (brand) Neurosurgical Sponges described in this submission is substantially equivalent to the predicate device.

Biocompatibility Testing:

PTFE is widely used in medical devices. Biocompatibility testing conducted included Cytotoxicity, Sensitization and Irritation testing. Testing 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 studies demonstrate the lack of toxicity of the device and its biocompatibility for use as a neurosurgical sponge. All studies were 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 peel testing to quantify the amount of force necessary to pull apart the substrate and PTFE layers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 20, 2013

American Surgical Company, LLC
c/o Mr. Michael Alouane
LSSBB Director of Quality
82 Sanderson Ave., Suite 212
Lynn, MA 01902

Re: K112598
Trade/Device Name: American Surgical Company Neurosurgical Sponges
Regulation Number: 21 CFR 882.4700
Regulation Name: Neurosurgical Paddie
Regulatory Class: Class II
Product Code: HBA
Dated: June 5, 2013
Received: June 6, 2013

Dear Mr. Alouane:

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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112598

Device Name: American Surgical Sponges (brand) Neurosurgical Sponges

Indications For Use:

The device is indicated for use by trained physicians during neurosurgical procedures to protect neural tissues from drying, abrasion, or contamination and to absorb fluids.

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

Victor Krauthamer -S
2013.06.20 16:48:38 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _____