K053158

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JAN 18 2006

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Optilene® Mesh LP
17 November 2005

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull
610-984-9072 (phone)
610-791-6882 (fax)

TRADE NAME: Optilene® Mesh LP

COMMON NAME: Surgical Mesh

CLASSIFICATION NAME: Mesh, Surgical, Polymeric

REGULATION NUMBER: 878.3300

PRODUCT CODE: FTL

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the *device name* is substantially equivalent to:

Ethicon Prolene Polypropylene Mesh (K962530)

Ethicon Prolene Soft Polypropylene Mesh (K001122)

DEVICE DESCRIPTION

Optilene Mesh LP is a synthetic implantable sheet for the reinforcement of connective tissue structures. It consists of monofilament polypropylene, which is knitted into a dimensionally stable, thin, and flexible net that is cut into various sizes and shapes.

INDICATIONS FOR USE

Optilene Mesh LP is indicated for hernioplasty and repair of other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

Both of these meshes are woven from monofilament polypropylene nonabsorbable suture material. Optilene Mesh LP and Prolene Mesh are also marketed in similar shapes and sizes that are packaged as sterile single use devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Mr. Matthew M. Hull, RAC
Manager, Regulatory Affairs
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K053158
Trade/Device Name: Optilene Mesh LP
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: January 4, 2006
Received: January 5, 2006

Dear Mr. Hull:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053158

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K053158

Device Name: ***Optilene Mesh LP***

Indications for Use:

Optilene Mesh LP is indicated for hernioplasty and repair of other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801 Subpart D) (per 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)

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

510(k) Number K053158