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SEP 1 5 2008

S.JACKSON, INC.
sutures & implants
15 Roth Street • P.O. Box 4487 • Alexandria, VA 22303

4.0 SUMMARY OF SAFETY AND EFFECTIVENESS

4.1 ADMINISTRATIVE INFORMATON

4.11 SPONSOR IDENTIFICATION

S. Jackson, Inc.
15 Roth Street
Alexandria, VA 22314
Contact Person: Mr. Janko Jackson, President
e-mail: supramid@mindspring.com
Telephone: 703-370-4900
Fax: 703-370-1679

4.12 ESTABLISHMENT REGISTRATION NUMBER: 1111225

4.13 OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D.
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
estrin@yourFDAconsultant.com
Tel: (301) 279 -2899
Fax: (301) 294-0126

4.14 DATE OF PREPARATION OF THIS SUMMARY: January 13, 2008

4.15 PROPRIETARY (TRADE) NAME: SupraMESH EXTRA™

4.16 COMMON NAME: Surgical Mesh

4.17 CLASSIFICATION NAME: Mesh, Surgical, Polymeric

4.18 REGULATION NUMBERS: 21 CFR 878.3300

4.19 PROPOSED REGULATORY CLASS: Class 2

4.20 DEVICE PRODUCT CODES: FTL

4.21 MEDICAL SPECIALTIES: General and Plastic Surgery

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4.2 DESCRIPTION OF THE DEVICE

SupraMESH EXTRA™ nylon mesh is an 18" x 18" mesh panel woven from USP size 3-0 **SUPRAMID EXTRA®** nylon suture (**FDA N80-838**). The nylon used to manufacture this **SUPRAMID EXTRA®** nylon suture (**FDA N80-838**) is nylon 6. The knit description of the **SupraMESH EXTRA™** nylon mesh panel is 1 x 1 Tricot stitch mesh.

S. Jackson, Inc. currently manufactures **Supramid Extra Surgical Mesh** (marketed as **SupraMESH®**) sterile mesh sheets under **FDA K831723, K852011** and **K831724**. **SupraMESH EXTRA™** nylon mesh is substantially equivalent to **Supramid Extra Surgical Mesh** (marketed as **SupraMESH®**) **FDA K831723, K852011** and **K831724** in design and function and shares the same indications for use.

4.3 INDICATIONS FOR USE

SupraMESH EXTRA™ nylon mesh is indicated for use as a hernia mesh and for plastic and reconstructive surgery.

4.4 PREDICATE DEVICES

Supramid Extra Surgical Mesh (marketed as **SupraMESH®**) **FDA K831723, K852011** and **K831724.**

4.5 SUBSTANTIAL EQUIVALENCE

SupraMESH EXTRA™ nylon mesh is substantially equivalent to **Supramid Extra Surgical Mesh** (marketed as **SupraMESH®**) **FDA K831723, K852011** and **K831724** with regard to indications for use and safety and effectiveness.

4.6 CONCLUSION

SupraMESH EXTRA™ nylon mesh raises no new safety/efficiency issues and has the same indications for use as the predicate device cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2008

S. Jackson, Inc.
% Estrin Consulting Group, Inc.
Mr. Norman R. Estrin
President
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K080216
Trade/Device Name: SupraMESH EXTRA™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: August 21, 2008
Received: August 22, 2008

Dear Mr. Estrin:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K080216

Indications for Use

510(k) Number (if known): **K080216**

Device Trade/Proprietary Name: SupraMESH EXTRA™

Indications for Use:

SupraMESH EXTRA™ nylon mesh is indicated for use as a hernia mesh and for plastic and reconstructive surgery.

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)

FOR M. MELKERSON

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

510(k) Number K080216