



K101287

99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

Section X
Summary of Safety and Effectiveness
(Prepared July 30, 2012)

AUG 30 2010

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

Trade Name: TephaFLEX Composite Mesh

Sponsor: Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701

Contact: Mary P. LeGraw, V.P., Regulatory Affairs

Device Classification Name: CFR §878.3300, Surgical Mesh

Product Code: OOD, OTO, OW T, OXL

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Tepha, Inc. – TephaFLEX Surgical Film
Tepha, Inc. – TephaFLEX Surgical Mesh

Indications for Use: TephaFLEX composite mesh is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: repair of colon and rectal prolapse (excluding rectocele) using an abdominal approach, sacral colposuspension and reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapse). The film side of the device may help minimize the potential for tissue attachment to the mesh in case of direct contact with the viscera.

Device Description: The TephaFLEX composite mesh is comprised of a layer of TephaFLEX knitted mesh with a layer of TephaFLEX film on one of its sides. The mesh is prepared from size 5-0 monofilament P4HB fiber and the film is a solid sheet of P4HB material. The knitted mesh side of the construct allows for tissue in growth while the film side provides a layer that physically separates the knitted mesh from underlying tissue and organ surfaces during the wound healing period to minimize tissue attachment to the mesh in case of direct contact with the viscera.

Safety and Performance: Mechanical and *in vivo* animal testing was performed based on recommendations identified in the FDA surgical mesh guidance document: The Guidance for the Preparation of a Pre-market



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Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. Long term *in vivo* strength retention was characterized via a subcutaneous *in vivo* implantation study with histological assessments out to 78 weeks. The mechanical and *in vivo* data collected determined the mesh to be substantially equivalent to the predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX composite mesh has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



Tepha, Incorporated
% Ms. Mary P. LeGraw
Vice President, Regulatory Affairs
99 Hayden Avenue, Suite 360
Lexington, Massachusetts 02421

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

Re: K101287

Trade/Device Name: TephaFLEX Surgical Mesh

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: Class II

Product Code: OOD, OTO, OWT, OXL

Dated: July 16, 2010

Received: July 19, 2010

AUG 24 2012

Dear Ms. LeGraw:

This letter corrects our substantially equivalent letter of August 30, 2010.

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 (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.

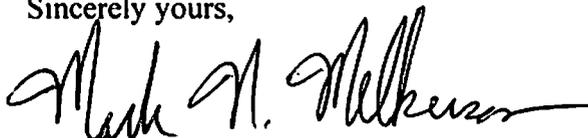
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

Enclosure

Indications for Use

510(k) Number (if known): K101287

Device Name: TephaFLEX Surgical Mesh

Indications for Use:

TephaFLEX® Composite Mesh is intended wherever temporary wound support is required, to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: repair of colon and rectal prolapse (excluding rectocele) using an abdominal approach, sacral colposuspension and reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapsed). The film side of the device may help minimize the potential for tissue attachment to the mesh in case of direct contact with the viscera.

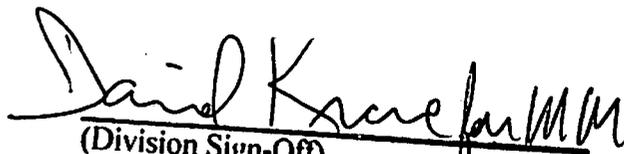
Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter _____
(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 Surgical, Orthopedic,
and Restorative Devices

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