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tepha

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99 Hayden Avenue
Suite 360
Lexington, MA 02421
Tel: 781.357.1700
Fax: 781.357.1701

Section X
Summary of Safety and Effectiveness

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® Surgical Film
Sponsor:	Tepha, Inc. 99 Hayden Avenue, Suite 360 Lexington, MA 02421 Telephone: 781.357.1700 Fax: 781.357.1701
Device Classification Name:	CFR §878.3300 Surgical Mesh
Classification:	According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Devices:	MAST Biosurgery, Inc. – Surgi-Wrap Film OsteoBiologics, Inc. -- PlastiFIlm Tepha, Inc. - TephaFLEX Absorbable Mesh
Device Description:	TephaFLEX surgical film is intended for temporary wound support, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential tissue attachment to the device in case of direct contact with the viscera.
Safety and Performance:	Physical and *in vivo* animal testing was performed on the TephaFLEX surgical film which determined the film to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.
Conclusion:	Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

Tepha, Inc.
% Ms. Mary P. LeGraw
Sr. Dirctor, Regulatory Affairs
99 Hayden Avenue
Lexington, Massachusetts 02421

Re: K072520
Trade/Device Name: TephaFLEX® Surgical Film
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL, NWJ
Dated: October 30, 2007
Received: October 31, 2007

Dear Ms. LeGraw:

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

K072520

Indications for Use

510(k) Number (if known): K072520

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended for temporary wound support, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Prescription Use: X AND/OR Over-The-Counter ___
(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)

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

510(k) Number K072520