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MAY 0 7 2013

Section IX
510(k) Summary
(April 18, 2013)

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® Melt blown Matrix

Sponsor:
Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421

Contact Person:
Mary P. LeGraw, V.P., Regulatory Affairs
Telephone: 781-357-1709
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Device Classification Name:
CFR §878.3300
Surgical Mesh – Product Code: OOD

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

Predicate Devices:
TephaFLEX Surgical Mesh – K113723
Cook Biodesign Surgisis Tissue Graft – K062696
Gore Bio-A Tissue Reinforcement – K033671
MAST Biosurgery Surgi-Wrap – K031995, K050332

Please see the attached Substantial Equivalence table comparing the TephaFLEX Meltblown Matrix to the predicate devices.

Device Description: The TephaFLEX Meltblown Matrix is a resorbable construct prepared from poly-4-hydroxybutyrate (P4HB) and is provided either non-dyed or dyed with D&C Violet No. 2. It is a porous, fibrous structure composed of thin P4HB fibers that result in a non-woven mesh like fabric. It is provided in single sheets of varying widths, lengths and shapes ranging from 1x1 to 10x14 inches.

Indications for Use: TephaFLEX Meltblown Matrix is intended to reinforce soft tissue where weakness exists in patients undergoing surgical procedures that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Safety and Performance: The P4HB material used to manufacture the TephaFLEX melt blown matrix is in compliance with the applicable parts of FDA's Class II Special Controls Guidance Document: Absorbable Poly(hydryoxybutyrate) Surgical Suture Produced by Recombinant DNA Technology. Mechanical testing, biocompatibility testing, 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-

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market Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. *In vivo* strength retention was characterized via a subcutaneous implantation study. The mechanical and *in vivo* data collected determined the product to be substantially equivalent to the predicate devices.

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

Substantial Equivalence Comparison Table

Characteristic	Tepha, Inc. Proposed TephaFLEX® Melt blown Matrix	Tepha, Inc. Predicate TephaFLEX® Mesh K113723	Cook Biotech Surgisis K062696	Gore Bio-A Tissue Reinforcement K033671	MAST Biosurgery, Inc. Surgi-Wrap K031955, K050332
Indications for Use	The TephaFLEX melt blown matrix is intended to reinforce soft tissue in surgical procedures that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	The TephaFLEX mesh is intended to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desire surgical result.	Surgisis is Intended for implantation to reinforce soft tissue. The device is intended for one-time use.	Bio-A Tissue Reinforcement is intended for use in the reinforcement of soft tissue. Examples of applications where the Bio-A may be used include, but are not limited to, hernia repair (in non-load bearing applications), muscle flap reinforcement, and general tissue reconstruction	SurgiWrap MAST Bioresorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, 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: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension. The absorbable protective film minimizes tissue attachment to the device in case of direct contact with the viscera.
Material	Poly-4-hydroxybutyrate (P4HB)	Poly-4-hydroxybutyrate (P4HB)	Porcine small intestinal submucosa	Poly(glycolide: trimethylene carbonate) copolymer	Polylactic acid (PLA)
Thickness	~ 1 mm	~ 0.6 mm	Nominal thickness ranging from 0.04 mm to 0.7 mm	~ 2 mm	20 – 1000 microns
Dyed, Non-dyed	Non-dyed & Dyed (D&C Violet #2)	Non-dyed & dyed (D&C Violet #2)	Non-dyed	Unknown	Undyed
Size	Single sheet sizes of: 1x2 through 10 X 12 inches	Single sheet sizes of: 1x2 through 12x14 inches	Single sheet size of : 2x3 through 7x10 cm	Available in single sheets and preformed, three-dimensional shapes.	Single sheet sizes of 25mm x 25mm to 500mm x 500mm
Performance Results Suture Pullout Tensile Strength	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent	Not tested	Substantially Equivalent
Absorption Profile	Absorption essentially complete within 12-18 months	Absorption essentially complete within 12-18 months	Unknown	Biobsorption process should be complete by the end of six months (labeling)	Absorption complete between 12-18 months depending on design.
Packaging	Foil packaging with removable Tyvek header	Foil packaging with removable Tyvek header	Inner pouch contained in outer bag composed of polymer film lined paper	Unknown	Tyvek film pouch in individual cardboard box
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide	Ethylene Oxide (EO)	Electron beam irradiation

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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

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

May 7, 2013

Re: K130326
Trade/Device Name: TephaFLEX® Meltblown Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OOD
Dated: April 18, 2013
Received: April 23, 2013

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. 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,
FOR

Peter D. Rumm -S

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

Enclosure

Indications for Use

510(k) Number (if known): Unknown

Device Name: TephaFLEX® Melt blown Matrix

Indications for Use:

TephaFLEX Melt blown Matrix is intended to reinforce soft tissue where weakness exists in patients undergoing surgical procedures that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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)

David Krause-S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130326