MAY 2 1 2014

TEPHA
MEDICAL DEVICES

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Section IX
510(k) Summary

(Prepared on February 28, 2014)

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: GalaFLEX® Mesh

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

Contact Person: Mary P. LeGraw, V.P., Regulatory Affairs
Telephone: 781-357-1709
Fax: 781-357-1701
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Device Classification Name: CFR §878.4494 – Product Code: OOD
Absorbable Poly(hydroxybutyrate) Surgical Mesh Produced by Recombinant DNA Technology

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 Mesh – K113723, K111946, K101287 and K070894

Allergan, SERI Surgical Scaffold – K123128

Please see attached Substantial Equivalence table comparing the GalaFLEX mesh to the predicate devices.

Device Description: GalaFLEX mesh is a sterile, knitted, resorbable mesh, constructed of non-dyed monofilament fibers made from poly-4-hydroxybutyrate (P4HB). It is provided in single sheets of varying widths, lengths and shapes, and may also be cut to the shape or size desired for a specific application.

Indications for Use: The GalaFLEX mesh is indicated for use as a transitory scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction.

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

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

Testing was also performed for conformance to ISO-10993 for biocompatibility. Tepha performed Cytotoxicity, Intracutaneous Irritation, Sensitization, Acute Systemic Toxicity, Pyrogenicity, Genotoxicity, and 12, 26 and 52 week Subcutaneous Implantation studies in rabbits. All testing yielded a non-toxic response.

Conclusion: Based on the indications for use, technological characteristics, and the results of safety and performance testing described above, the GalaFLEX mesh has been shown to be substantially equivalent to predicate devices used for the same clinical indications under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 21, 2014

Tepha, Incorporated
Mr. Andrew Joiner
President and CEO
99 Hayden Avenue, Suite 360
Lexington, Massachusetts 02421

Re: K140533
Trade/Device Name: Galaflex Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OOD
Dated: February 28, 2014
Received: March 4, 2014

Dear Mr. Joiner,

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita Ashar, MD, MBA, FACS
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: GalaFLEX® Mesh

Indications for Use:

GalaFLEX mesh is indicated for use as a transitory scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction.

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)

Peter L. Hudson -S