TEPHA
MEDICAL DEVICES

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

Section X
510(k) Summary

(Prepared on July 26, 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 Braided Suture

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

SEP 05 2013

Contact Person: Mary P. LeGraw, V.P., Regulatory Affairs
Telephone: 781-357-1709
Fax: 781-357-1701
Email: legraw@tepha.com

Device Classification Name: CFR §878.4494 – Product Code: NWJ
Absorbable Poly(hydroxybutyrate) Surgical Suture 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 Absorbable Suture - K052225, K082178
Tornier, Inc., BioFiber Suture – K122487, K130422
Ethicon, Inc., Perma-Hand Silk Braided Suture – K930360
U.S. Surgical (Covidien), Dexon S Suture – K972566
Ethicon, Inc., Vicryl Suture – K022269

Please see attached Substantial Equivalence table comparing the TephaFLEX Braided suture to the predicate devices.

Device Description: TephaFLEX suture is a sterile, braided, surgical suture constructed of poly-4-hydroxybutyrate (P4HB). The suture consists of an inner core of multifilament fibers covered by a braided sheath made of multifilament fibers. The suture is provided dyed (D&C Violet No. 2) or un-dyed and is offered in a variety of cut lengths, with or without needles attached.

Indications for Use: The TephaFLEX sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery, or ophthalmic surgery.

Safety and Performance: All testing was performed in compliance with the FDA Guidance: Class II Special Controls Guidance: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology.

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Physical/mechanical testing performed on the TephaFLEX suture verified conformance to USP 33 for absorbable surgical sutures, including <861> Suture Diameter, <881> Knot Pull Tensile Strength, and <871> Needle Attachment Strength.

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, 52 and 78 week Subcutaneous Implantation studies in rabbits. All testing yielded a non-toxic response.

In vivo implantation studies were conducted in rabbits to demonstrate rates of tensile strength and mass loss. Results show the *in vivo* strength retention of the TephaFLEX braided suture to be equivalent to the published strength retention of the predicate devices with the same clinical indications over the critical healing period. Therefore, the TephaFLEX braided suture is equivalent to the predicate device in regard to its strength retention profile.

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

Table 10
Substantial Equivalence Comparison Table

Characteristic	Tepha, Inc. TephaFLEX Braided Suture	Tepha, Inc. TephaFLEX Absorbable Suture K052225, K081099, K082178	Ethicon, Inc., Perma-Hand Silk Suture K930360	Covidien/US Surgical Dexon Braided Suture K972566
Indications for Use	Indicated for use in soft tissue approximation and/or ligation but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic surgery.	Indicated for use in soft tissue approximation and/or ligation but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six months) is desirable.	Perma-Hand sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	Braided Dexon S sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.
Material	Poly-4-hydroxybutyrate (P4HB)	Poly-4-hydroxybutyrate (P4HB)	Organic fibroin protein derived from domesticated species Bombyx mor (B. mori). Dyed black and coated with a special wax mixture	Composed of the homopolymer of glycolic acid. Coated with Polycaprolate, a co-polymer of glycoloide and epsilon-caprolactone.
Dyed, Undyed	Dyed and Un-dyed	Dyed and Un-dyed	Dyed	Dyed & Un-dyed
Filament Type	Multifilament	Monofilament	Multifilament	Multifilament
Size	2 (various lengths) with or w/out needles attached	5-0 through 2 (various lengths) with or w/out needles attached	9-0 through 5 (various lengths) with or w/out needles attached	8-0 through 2 (various lengths)
Suture Diameter **Knot Pull Strength** **Needle Attachment Strength**	All characteristics meet USP Requirements, except for diameter.	All characteristics meet USP Requirements, except for diameter.	All characteristics meet USP Requirements, except for diameter.	All characteristics meet USP requirements.
Absorption Profile	Approximate % Strength remaining (BSR) **Size 2** 2 - 4 weeks: ~60% 8 -12 weeks: ~35% 26 weeks: ~8%	Approximate % Strength remaining (BSR): **Sizes:** 5-0, 4-0 / 3-0, 2-0 / 0, 1, 2 4 weeks: ~60% ~60% ~90% 8 weeks: ~30% ~50% ~80% 12 weeks: ~20% ~40% ~60% 26 weeks: ~0% ~30% ~30%	From IFU While silk sutures are not absorbed, per se, progressive degradation of the proteinaceous silk fiber *in vivo* may result in gradual loss of all of the suture's strength over time.	Approximate % strength remaining (BSR): 2 weeks (6-0 and larger): ~65% 3 weeks (6-0 and larger): ~35% 2 weeks (7-0 and smaller): ~55% 3 weeks (7-0 and smaller): ~20%

	Absorption essentially complete within 12-18 months	Absorption essentially complete within 12 – 24 months	From Ethicon Wound Closure Manual: Surgical silk loses tensile strength when exposed to moisture and should be used dry. Although silk is classified by the USP as a non-absorbable suture, long-term in vivo studies have shown that it loses most or all of its tensile strength in about 1 year and usually cannot be detected in tissue after 2 years. Thus, it behaves in reality as a very slowly absorbing suture.	Absorption is essentially complete between 60 and 90 days
Packaging	Foil packaging with removable Tyvek header	Foil packaging with removable Tyvek header	Tyvek with foil inner pack	Foil package / Tyvek
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)

Table 10 (continued)

Characteristic	Ethicon - Vicryl Braided Suture - K022269	Tornier – BioFiber Suture -K122487, K130422
Indications for Use	Coated Vicryl suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for usue in cardiovascular and neurological tissues	Indicated for use in soft tissue approximation and/or ligation but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic surgery.
Material	Co-polymer of 90% glycolide and 10% L-lactide. Coating of equal parts of co-pololymer of glycolide and lactide with calcium stearate	Poly-4-hydroxybutyrate (P4HB)
Dyed, Undyed	Dyed & Un-dyed	Dyed & Un-dyed
Filament Type	Multifilament	Multifilament
Size	6-0 though 3 (various lengths) with or without needles attached	2 (various lengths), with or w/out needles attached
Suture Diameter **Knot Pull Strength** **Needle Attachment Strength**	All characteristics meet USP requirements, except for diameter	All characteristics meet USP Requirements, except for diameter
Absorption Profile	Approximate % Strength remaining (BSR): 2 weeks: ~75% 3 weeks (6-0 and larger): ~50% 3 weeks (7-0 and larger): ~40% 4 weeks (6-0 and larger): ~25% Absorption is essentially complete between 56 and 70 days	Approximate % Strength remaining (BSR) 2 - 4 weeks: ~60% 8 -12 weeks: ~40% 26 weeks: ~20% Absorption essentially complete within 18-24 months
Packaging	Tyvek with foil inner pack	Tyvek with foil inner pack
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)

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

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

September 5, 2013

Re: K132348
Trade/Device Name: TephaFLEX Braided Suture
Regulation Number: 21 CFR 878.4494
Regulation Name: Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology
Regulatory Class: Class II
Product Code: NWJ
Dated: July 26, 2013
Received: July 29, 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 contact 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. 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,

Mark N. Melkerson -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): Not Assigned

Device Name: TephaFLEX Braided Suture

Indications for Use:

TephaFLEX braided sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

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: K132348