May 27, 2021

Tepha, Inc.
Jodie Giordano
Sr Regulatory Specialist
99 Hayden Avenue, Suite 360
Lexington, Massachusetts 02421

Re: K211307
Trade/Device Name: GalaSTITCH Absorbable Monofilament 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: April 28, 2021
Received: April 29, 2021

Dear Dr. Giordano:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Cindy Chowdhury, Ph.D., MBA
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211307

Device Name
GalaSTITCH Absorbable Monofilament Suture

Indications for Use *(Describe)*
GalaSTITCH™ Absorbable Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery, or ophthalmic surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submitter

Company Name:	Tepha, Inc.
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Telephone:	781-475-8849
Fax:	781-357-1701
Contact Person:	Jodie Giordano, PhD
	Senior Regulatory Affairs Specialist
Date Prepared :	April 28, 2021

2. Device

Trade Name:	GalaSTITCH™ Absorbable Monofilament Suture
Classification Name:	Absorbable Poly(hydroxybutyrate) Surgical Suture produced by recombinant DNA technology
Classification Reg/Panel:	CFR §878.4494 / General and Plastic Surgery
Product Code:	NWJ

3. Predicate Device

Predicate Name/510(k) Number	TephaFLEX™ Absorbable Monofilament Suture (K082178)
Reference Devices:	Stratafix Spiral PDS Plus **(**K192144)
	Maxon Monofilament (K990951)

Device Description

GalaSTITCH Absorbable Monofilament Suture (GalaSTITCH) is identical to the predicate TephaFLEX Absorbable Monofilament Suture (TephaFLEX) in regard to materials, design, and manufacturing processes. The product is being rebranded and will be commercialized by Tepha, Inc.'s wholly owned subsidiary, Galatea. GalaSTITCH is constructed of poly-4-hydroxybutyrate (P4HB) which is a biologically derived polymer that is extruded into monofilament fibers. The sterile P4HB suture is offered as undyed (clear) and dyed (violet) and meets all standards (except diameter) set by the United States Pharmacopeia (USP) for synthetic absorbable sutures. P4HB bioabsorbs through a process of hydrolysis and hydrolytic enzymatic digestion.

4. Indications for Use

GalaSTITCH™ Absorbable Monofilament Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery, or ophthalmic surgery.

The indications for use statement for GalaSTITCH is identical to the TephaFLEX predicate device.

5. Comparison of Technological Characteristics with the Predicate Device

The proposed GalaSTITCH suture is substantially equivalent to TephaFLEX suture because it is identical in regard to materials, design, manufacturing processes, and intended use. The following modifications are exclusive to product labeling do not impact the fundamental scientific technology and intended use of the previously cleared device.

The purpose of this Special 510(k) submission is to notify the FDA of two main changes being made to the labeling of the predicate TephaFLEX suture (K082178):

1. The TephaFLEX Absorbable Monofilament Suture will be rebranded (renamed) and will be commercialized through Tepha's wholly owned subsidiary, Galatea, as the GalaSTITCH Absorbable Monofilament Suture.
2. The predicate TephaFLEX IFU currently includes a contraindication statement as follows:
   TephaFLEX™ Absorbable Monofilament sutures should not be used where permanent support is required or in conjunction with prosthetic devices or grafts.

For clarification purposes, Tepha is adding the content in bold to the contraindication statement as follows:

> *GalaSTITCH™ absorbable monofilament surgical suture should not be used where permanent support is required or in conjunction with* ***permanent*** *prosthetic devices or grafts* ***(e.g., heart valves or synthetic grafts)***.

6. Safety and Performance Data

There have been no changes to the P4HB material, design specifications, or the manufacturing processes for purposes of this submission. The GalaSTITCH suture is identical to the TephaFLEX predicate; therefore, no additional testing was necessary to demonstrate safety and performance.

7. Conclusions

GalaSTITCH™ Absorbable Monofilament Suture is substantially equivalent to the predicate device based on the identical intended use and identical technological characteristics, and clarifying labeling changes that are consistent with language cleared in the reference device submissions.