DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 23, 2017

Tepha, Inc.
Ms. Connie H. Garrison
Vice President, Regulatory Affairs
99 Hayden Avenue
Lexington, MA 02421

Re: K162922
Trade/Device Name: GalaFORM, 3D
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OOD
Dated: January 17, 2017
Received: January 22, 2017

Dear Ms. Garrison:

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 S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162922

Device Name
GalaFORM 3D

Indications for Use *(Describe)*
GalaFORM 3D scaffold is indicated for use as a bioresorbable 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. GalaFORM 3D scaffold is also indicated for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

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

SUBMITTED BY:

Company Name:	Tepha, Inc.
Address:	99 Hayden Avenue Suite 360 Lexington, MA 02421
Telephone:	781-357-1709
Fax:	781-357-1701

CONTACT PERSON:	Connie H. Garrison, MBA, RAC
DATE PREPARED:	October 14, 2016
TRADE NAME:	GalaFORM™ 3D
COMMON and CLASSIFICATION NAME:	Mesh, surgical, absorbable, plastic and reconstructive surgery
CLASSIFICATION REG/PANEL:	CFR §878.3300 / General and Plastic Surgery
PROCODE:	OOD

PREDICATE DEVICES:

K161092 GalaSHAPE™ scaffold
K140533 GalaFLEX® scaffold

DEVICE DESCRIPTION:

GalaFORM 3D scaffold is a bioresorbable surgical mesh manufactured from poly-4-hydroxybutyrate (P4HB). P4HB is produced from a naturally occurring monomer and is processed into monofilament fibers and knitted into a surgical scaffold. The scaffold has a 3D curvature supported with a P4HB rim designed to promote better conformance with a patient's anatomy in locations in which a flat design does not easily conform. P4HB bioresorbs through a process of hydrolysis and hydrolytic enzymatic digestion. It has been developed to optimize resorption rate and prolong strength retention in order to provide support throughout the expected period of healing. Although the scaffold loses strength with time, its porous construction was designed to allow native tissue ingrowth and gradual transfer of load from the scaffold to the tissue.

Pre-clinical implantation studies indicate that GalaFORM 3D scaffold retains approximately 70% of its strength at 12 weeks. Bioresorption of the scaffold material will be essentially complete within 18-24 months. The outer rim may be palpable throughout the expected period of healing.

INDICATIONS FOR USE/INTENDED USE:

GalaFORM 3D scaffold is indicated for use as a bioresorbable 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. GalaFORM 3D scaffold is also indicated for the repair of fascial defects that require the addition of a reinforcing

or bridging material to obtain the desired surgical result.

The indications for use statement for GalaFORM 3D is identical to that of the predicates.

SUMMARY of TECHNOLOGICAL CHARACTERISTICS:

Results from performance testing based on "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", dated March 2, 1999, demonstrate substantial equivalence of GalaFORM 3D to the predicate devices**.** GalaFORM 3D is unchanged in materials, knit construction, and bioresorption profile from the predicates. The only difference between the predicate, GalaSHAPE 3D, and the subject device is the addition of a P4HB rim along the perimeter of the mesh to provide a stiffer edge and curvature. Both the predicate devices and GalaFORM 3D are ethylene oxide sterilized and intended for single use only. The devices are suitable 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.

BIOCOMPATIBILTY:

Biocompatibility testing of the device family was conducted per the categorization principles in ISO 10993-1:2009. Based on the standard, the device was categorized as an implant device in contact with tissue and bone, and having a duration of contact of greater than 30 days (permanent). Results from the testing support the biocompatibility and safety of the subject device.

ANIMAL STUDIES:

An animal study was conducted to characterize the tissue response, resorption profile, and strength characteristics of the device after implantation to verify no changes to these characteristics due to the modified manufacturing process to add a rim to the edge of the mesh and create a three-dimensional shape. In this study, the subject device and the predicate GalaFLEX scaffold, were subcutaneously implanted in rabbits. Necropsies were performed at 4, 8, 12 and 40 week time points. The results from the study support the comparability of GalaFORM 3D with the predicates. The local tissue reaction was judged to be similar between the predicate and the shaped mesh, and there was no statistically significant difference ($p>0.05$) in burst strength between the curved mesh and the GalaFLEX sample groups at each of the time points indicating a comparable bioresorption profile. Comparability of the resorption profile of GalaFORM 3D and the predicate was also supported by similar molecular weights of the polymer at each of the time points.

CONCLUSION:

Based on the intended use, technological characteristics, biocompatibility studies, and animal testing, GalaFORM™ 3D is substantially equivalent to the predicate devices.

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