August 19, 2021

Tepha, Inc.
Connie Garrison
SVP, Regulatory, Clinical and Quality Systems
99 Hayden Avenue, Suite 360
Lexington, MA 02421

Re: K202425
Trade/Device Name: SurgiLattice scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 15, 2021
Received: July 20, 2021

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. 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 and Part 809); 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 Deborah Fellhauer
Acting 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)*
K202425

Device Name
SurgiLattice™ scaffold

Indications for Use *(Describe)*
SurgiLattice™ scaffold is indicated for use as a bioabsorbable 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. SurgiLattice scaffold is also indicated for the repair of hernia and other fascial defects that require the addition of a reinforcing 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

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of SurgiLattice scaffold.

SUBMITTED BY:

Company Name:	Tepha, Inc.
Address:	99 Hayden Avenue Suite 360 Lexington, MA 02421
Telephone:	781-357-1777
Fax:	781-357-1701

CONTACT PERSON:	Connie Garrison
DATE PREPARED:	13 August 2021
TRADE NAME:	SurgiLattice™ scaffold
COMMON NAME:	Surgical mesh
CLASSIFICATION NAME/PANEL:	Mesh, surgical, polymeric CFR §878.3300 / General and Plastic Surgery
PROCODE:	FTL

PREDICATE DEVICE	K140533
TRADE NAME:	GalaFLEX® scaffold
COMMON NAME:	Surgical mesh
CLASSIFICATION NAME/PANEL:	Absorbable Poly(hydroxybutyrate) Surgical Mesh Produced by Recombinant DNA Technology CFR §878.3300 / General and Plastic Surgery
PROCODE:	OOD

DEVICE DESCRIPTION:

SurgiLattice scaffold is a bioabsorbable surgical mesh manufactured from poly-butylene succinate (PBS). PBS is an absorbable polymer that is processed into monofilament fibers and knitted into a surgical scaffold. PBS degrades through the process of hydrolysis, is absorbed over time, and is ultimately eliminated as CO_2 and H_2O. It has been developed to optimize absorption 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 SurgiLattice scaffold retains approximately 88% of its strength at 12 weeks, with minimal residual strength remaining at 78 weeks based on in vitro degradation studies.

INDICATIONS FOR USE/INTENDED USE:

SurgiLattice™ scaffold is indicated for use as a bioabsorbable 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. SurgiLattice scaffold is also indicated for the repair of hernia and other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result.

COMPARISON of TECHNOLOGICAL CHARACTERISTICS:

SurgiLattice scaffold has an indications statement that is the same as the predicate, with the exception of bridging repair which is not included for the subject device. The technological characteristics and principles of operation are the same. The minor technological difference related to the biomaterial composition does not raise new issues of safety or effectiveness. The data demonstrate that SurgiLattice scaffold is substantially equivalent to the predicate device.

Both the subject and predicate devices are absorbable surgical mesh devices that slowly hydrolyze resulting in a gradual loss of strength and mass for the bulk material. In the body, the hydrolytic degradation products of PBS, 1,4-butanediol and succinic acid, are further metabolized through 4-hydroxybutyric acid (4HB) and succinic acid and eliminated from the body primarily by metabolism via the Krebs Cycle. In a similar degradation pathway, the predicate device, composed of poly-4-hydroxybutyrate (P4HB), hydrolyzes to 4-hydroxybutryate (4HB), which is also further metabolized into succinic acid and likewise is eliminated from the body via the Krebs Cycle.

The physical and mechanical properties of the subject and predicate device are also comparable. Results from performance testing based on “Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh”, dated March 2, 1999, demonstrate comparable mesh thickness, density, pore diameter, mesh knit characteristics, burst strength, bending stiffness, tensile strength, suture pull-out, and tear strength. Both products have the same macroporous, monofilament warp knit construction.

PERFORMANCE DATA:

The performance characteristics of SurgiLattice scaffold were established via comprehensive studies of physical and mechanical properties, biocompatibility testing per ISO 10993 including a Toxicological Risk Assessment based on extractables and leachables data per ISO 10993-18, shelf life testing, lifecycle evaluation in GLP rabbit studies per ISO 10993-6 including implantation of pre-degraded biomaterial representative of longer term in-vivo data, in vitro degradation studies, and functional performance in a large animal model study.

Bench testing of physical and mechanical characteristics, and shelf life studies using real-time and accelerated aging were performed with passing results. Biocompatibility testing of SurgiLattice scaffold 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 panel of testing, specifically cytotoxicity, irritation or intracutaneous reactivity, maximization-sensitization, acute systemic toxicity, material-mediated pyrogenicity, genotoxicity (bacterial reverse mutation), genotoxicity (mouse lymphoma assay), hemolysis, subacute/subchronic/chronic local toxicity, subcutaneous implantation with histology (4, 12 and 26 weeks), subcutaneous implantation with histology using partially-degraded mesh(representing 116 weeks), coupled with a toxicological assessment conducted per ISO 10993-18, support the biocompatibility and safety of the subject device.

A study was conducted to evaluate dimensional, mechanical, morphologic, and histological properties of SurgiLattice at 4, 8, 12 and 26 weeks following subcutaneous dorsal implantation in a rabbit model, as compared to GalaFLEX Scaffold. The initial strength, the strength retention profile, and the degradation profile of the SurgiLattice™ scaffold were comparable to the predicate. The results from this study support the in vivo comparability of SurgiLattice™ scaffold with the predicate, GalaFLEX scaffold.

A second study was conducted to evaluate the local tissue reaction using SurgiLattice scaffold which had undergone accelerated hydrolytic degradation followed by 26 weeks implantation which simulated a final tissue assessment timepoint of approximately 116 weeks. This study was designed to assess the host response upon essentially complete mechanical and molecular weight polymer degradation. Microscopically, SurgiLattice scaffold caused minimal or no reaction and was comparable to the predicate device.

SurgiLattice scaffold was further evaluated in a functional porcine model of hernia repair through assessment of repair site mechanics (burst strength and stiffness), morphologic properties (fiber diameter/surface roughness), molecular weight, and histology. The results support substantial equivalence of SurgiLattice scaffold to the predicate.

CONCLUSION:

Based on the indications for use, technological characteristics, and the summary of data submitted, Tepha, Inc. has determined that the proposed subject device, SurgiLattice scaffold is substantially equivalent to the currently marketed predicate device, GalaFLEX scaffold. Performance testing, including in vivo data and a comprehensive assessment of biocompatibility, demonstrated that the device functions as intended without raising new questions of safety or effectiveness.