510(k) SUMMARY

SUBMITTED BY:
Company Name: Allergan
Address: 200 Boston Avenue, Suite 3700
          Medford, MA 02155
Telephone: 781-658-2800
Fax: 781-723-7790

CONTACT PERSON: Connie H. Garrison, MBA, RAC
DATE PREPARED: March 7, 2013
TRADE NAME: SERITM Surgical Scaffold
COMMON and CLASSIFICATION NAME: Mesh, surgical, absorbable, plastic
and reconstructive surgery
CLASSIFICATION REG/panel: CFR §878.3300 / General and Plastic
Surgery
PROC0DE:

PREDICATE DEVICES:
K080442 SERITM Surgical Scaffold
K083898 TEl Biosciences SurgiMend Collagen Matrix
K810428 Ethicon Vicryl Knitted Mesh

DEVICE DESCRIPTION:
SERITM Surgical Scaffold is a knitted, multifilament, bioengineered, long-term
biodesorbable scaffold. It is derived from silk that has been BIOSILKTM purified to yield
ultra pure fibroin. The device is a mechanically strong and biocompatible bioprotein.
SERITM Surgical Scaffold is a sterile, single use only product and is supplied in a variety
of sizes ready for use in open or laparoscopic procedures. The scaffold is flexible and
well-suited for delivery through a laparoscopic trocar. It is tear resistant, with excellent
suture retention, and can be cut in any direction. SERITM Surgical Scaffold provides
immediate physical and mechanical stabilization of a tissue defect through its strength
and porous (scaffold-like) construction.

SERITM Surgical Scaffold is designed to slowly bioresorb in parallel to
neovascularization and native tissue ingrowth which results in eventual replacement of
SERITM with native tissue. As bioresorption occurs, load bearing responsibility is
transferred to the new tissue ingrowth such that mechanical integrity is maintained at the
site.

INDICATIONS FOR USE/INTENDED USE:
SERITM Surgical Scaffold is indicated for use as a transitory scaffold for soft tissue
support and repair to 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.
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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 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, FOR

Peter D. Rumm-S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
4. **INDICATIONS FOR USE STATEMENT**

**510(k) Number (if known):** K123128

**Device Name:** SERI™ Surgical Scaffold

**Indications for Use:**

SERI Surgical Scaffold is indicated for use as a transitory scaffold for soft tissue support and repair to 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 Use (Part 21 CFR 801 Subpart D) (21 CFR 807 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

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123128