



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

September 22, 2017

Sofregen Medical, Inc.  
Anh Hoang, Ph.D.  
Chief Scientific Officer  
200 Boston Avenue, Suite 1100  
Medford, MA 02155

Re: K172545

Trade/Device Name: SERI<sup>®</sup> Contour  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: Class II  
Product Code: OXF  
Dated: August 14, 2017  
Received: August 23, 2017

Dear Dr. Hoang:

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

## Indications for Use

510(k) Number (if known)

K172545

Device Name

SERI® Contour

Indications for Use (Describe)

SERI® Contour 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the SERI<sup>®</sup> Contour is provided below.

## **1. SUBMITTER**

Sofregen Medical, Inc.  
200 Boston Avenue, Suite 1100  
Medford, MA 02155

Contact Person: Anh Hoang, Ph.D.  
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Date Prepared: August 16, 2017

## **2. DEVICE**

Name of Device: SERI<sup>®</sup> Contour  
Common Name: Surgical Mesh  
Classification Regulation: 21 CFR 878.3300  
Regulatory Class: II  
Product Code: OXF  
Panel: General and Plastic Surgery

## **3. PREDICATE DEVICE**

Predicate Device: SERI<sup>®</sup> Surgical Scaffold (K123128)  
Reference Device: None

## **4. DEVICE DESCRIPTION**

SERI<sup>®</sup> Contour is a knitted, multifilament, bioengineered, long-term bioresorbable scaffold. It is derived from pure silk fibroin. The device is a mechanically strong and biocompatible protein mesh. SERI<sup>®</sup> Contour 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. SERI<sup>®</sup> Contour provides immediate physical and mechanical stabilization of a tissue defect through its strength and porous (scaffold-like) construction.

## **5. INDICATION FOR USE**

SERI<sup>®</sup> Contour 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.

## **6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

The subject SERI® Contour has undergone a design change to increase the pore size and knit construction of the mesh compared to the predicate SERI® Surgical Scaffold (K123128). All other material and processing parameters are the same for the production and sterilization of Contour and Scaffold, independent of the pore size and knit pattern. The increased pore size of Contour and knitted construction in both material directions increase the mesh's elasticity that results in a more pliable and drapable surgical mesh. The design change updates handleability in response to clinical feedback, but maintain performance characteristics to accommodate soft tissue repair and support.

## **7. PERFORMANCE DATA**

The differences in surgical mesh specifications between Contour and Scaffold do not affect production, biocompatibility, and intended use of the product. Introducing greater pore area into the Contour design reduces overall density and burst strength of the mesh compared to the Scaffold predicate. Burst strength specifications for both devices were established to exceed peak forces in the abdomen. The fully knitted construction of Contour increases the elasticity and drapability of the mesh compared to Scaffold. When evaluated in a large animal model, Contour supported tissue ingrowth and equivalent burst strength to Scaffold at 3, 6, and 12-month evaluation.

## **8. CONCLUSIONS**

The design change for SERI Contour introduces larger pores into a fully knitted mesh format, increasing both pliability and drapability requested from clinical feedback of SERI Scaffold. Independent of the mesh pattern, silk processing, mesh production, sterilization, biocompatibility, and intended use are identical to the predicate Scaffold surgical mesh. Burst stress for Contour was verified to perform in excess of the maximum calculated, worst case scenario of abdominal pressure. *In vivo* performance testing in a large animal model resulted in equivalent burst stress for Contour and Scaffold, confirming soft tissue formation through 1-year evaluation.

In conclusion, based on the same intended use and design change introducing larger pores in a fully knitted mesh, the subject SERI® Contour is substantially equivalent to the predicate SERI® Surgical Scaffold (K123128).