K080442

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510(k) Summary

SUBMITTED BY:

Company Name:	**Serica Technologies, Inc.**
Address:	**200 Boston Avenue, Suite 3700**
	Medford, MA 02155
Telephone:	**781-395-5552**
Fax:	**781-395-3330**

CONTACT PERSON:	**Connie H. Garrison, MBA, RAC**
DATE PREPARED:	**February 12, 2008**
TRADE NAME:	***SeriScaffold*™ surgical mesh**
COMMON and CLASSIFICATION NAME:	**Surgical Mesh**
CLASSIFICATION REG/PANEL	**General and Plastic Surgery / CFR §878.3300**
PROCODE	**FTL**

SUBSTANTIALLY EQUIVALENT TO:

SeriScaffold surgical mesh is substantially equivalent to predicate surgical mesh products legally marketed in the United States as follows: Bard Mesh® (pre-amendment), Vicryl™ Mesh (K810428), Mersilene™ Mesh (pre-amendment) and Permacol® Surgical Implant (collagen) (K043366). Any minor differences between *SeriScaffold* surgical mesh and the predicate devices do not introduce new safety or performance issues.

DESCRIPTION of the DEVICE:

SeriScaffold surgical mesh is a knitted, multi-filament, bioengineered, silk mesh. It is mechanically strong, biocompatible, and long-term bioresorbable. *SeriScaffold* surgical mesh is a sterile, single use only mesh and is supplied in a variety of shapes and sizes ready for use in open or laparoscopic procedures. The device is flexible and well suited for delivery through a laparoscopic trocar due to its strength, tear resistance, suture retention, and ability to be cut in any direction. *SeriScaffold* surgical mesh provides immediate physical and mechanical stabilization of a tissue defect through the strength and porous (scaffold-like) construction of its mesh.

INDICATIONS FOR USE/INTENDED USE:

SeriScaffold surgical mesh 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.

SUMMARY of TECNOLOGICAL CHARACTERISTICS:

Results from performance testing based on "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", March 2, 1999 demonstrates substantial equivalence of *SeriScaffold* surgical mesh to predicate surgical mesh products. Results from an *in vitro* bioresorption study characterize the bioresorption properties of *SeriScaffold* surgical mesh versus Vicryl Mesh which support the long-term bioresorption property of *SeriScaffold* surgical mesh. Biocompatibility was conducted according to

internationally recognized standards and all results indicate the device is biocompatible. Data from an *in vivo* rabbit study further support the bioresorption and biocompatibility properties of the device.

CONCLUSION:

Data from bench testing, biocompatibility testing, and an *in vivo* rabbit study demonstrate that *SeriScaffold* surgical mesh is safe and effective and is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

Serica Technologies, Inc.
% Ms. Connie Garrison, MBA, RAC
VP, Regulatory Affairs and Quality
Assurance
200 Boston Avenue, Suite 3700
Medford, Massachusetts 02155

Re: K080442
Trade/Device Name: SeriScaffold™ surgical mesh
Regulation Number: 21 CFR 878.3300
Device Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: October 15, 2008
Received: October 16, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *SeriScaffold*™ surgical mesh

Indications For Use:

SeriScaffold™ surgical mesh 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for akm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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