Surgical Structure
Improving Hernia Repair with Mesh GPS Technology

Mesh GPS
Retrievable Deployment Device for Ventral Hernia Repair

510(K) SUMMARY
Mesh GPS™ Device
510(k) Number K_____

MAR 15 2010

Company Name

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Contact Person

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Trade/Proprietary Name

Mesh GPS device

Classification Name

laparoscope, general & plastic surgery

Classification:

FDA has classified this type of device as class II, product code OQL for a "mesh deployment balloon" under 21 CFR §878.3300, and they are reviewed by the Plastic and Reconstructive Surgery Branch.

Predicate Devices

- Davol Delivery System (currently marketed as PrecisionPass Laparoscopic Delivery Device), K041641 (Davol Inc.).
- Bard Composix® L/P Mesh, K061754 (Davol, Inc.).
- Biomesh CA.B.S.'Air, K072962 (Cousin Biotech S.A.S).
- DualMesh EMERGE Biomaterial and DualMesh EMERGE PLUS Biomaterial, K022782 (W.L. Gore and Associates, Inc).
- Modified SPACEMAKER System, K042412 (United States Surgical). This is a special 510k on the SPACEMAKER* Dissection Balloon, K973046.
- Hernia Mesh Stabilizer, K981598 (Medivices Inc.).
- PAJUNKs Balloons and Balloon systems, K090631 (Pajunk Medical Systems).
- Rebound HRD, K063671 (Minnesota Medical Development, Inc. (MMDI)).

Intended Use

The *Mesh GPS* device is intended to be used to facilitate the delivery of soft tissue prosthetics during the laparoscopic repair of hernia.

Device Description

The *Mesh GPS* facilitates the delivery of soft tissue prosthetics during the laparoscopic ventral hernia repair, by assisting surgeons with maneuvering, spreading and deploying hernia repair meshes in the abdominal cavity, resulting in easier final fixation to the abdominal wall and shortening of OR time.

The device is comprised of three main components: an inflatable spreading balloon; an adaptor and an inflation unit/pump. The device's three components are sterile, single use and packed within a double pouch.

The Spreading Inflatable Balloon is composed of biocompatible Thermoplastic Polyurethane (TPU). The balloon is the main component of the device which supports and facilitates the navigation and deployment of a mesh within the abdominal cavity. It is reversibly attached to the mesh using the mesh connectors, before its insertion into the body, then rolled together. Once located in the abdominal cavity it is easily spread at the desired location by inflating it using the external Inflation Pump. The balloon comes in several sizes/configurations to enable its use with a wide variety of meshes available on the market. **The Inflation Tube** is composed of biocompatible Thermoplastic Polyurethane (TPU). Its purpose is to transport the air from the external **Inflation Pump** into the Spreading balloon and inflate it and to externally grab the balloon by the suture passer and position it at the proper location within the abdominal cavity.

Performance Data

The *Mesh GPS* components that contact the body were tested for biocompatibility according to ISO 10993-1 standard and Blue Book Memo G95-1 requirements.

The *Mesh GPS* device underwent a full battery of bench tests and animal studies to demonstrate its safe and effective performance in delivering, spreading/deployment, facilitating the attachment of the mesh to the abdominal wall and withdrawing from the abdominal cavity. Tests were performed with various market-cleared mesh types and sizes using all *Mesh GPS* device models.

In general the studies included performance testing as well as various mechanical testing for design features that are different from the predicate devices, e.g. device components connection strength/integrity, burst/over inflation testing, withdrawal test, performance & usability tests, etc. All tests met the acceptance criteria demonstrating that the device is safe, effective, performs as intended, and is substantially equivalent to its predicates.

Animal studies conducted on pigs, using a wide variety of market-cleared meshes, revealed that mesh delivery and deployment using the *Mesh GPS* device is safe and effective. The procedure is simple, the delivery and deployment are effective without needing any additional activities by the surgeons.

All these tests demonstrate that the *Mesh GPS* is a safe and effective device for facilitating the delivery of soft tissue prosthetics during the laparoscopic repair of

hernia without raising any new safety or effectiveness issues.

Conclusion:

Surgical Structure Ltd. believes that, based on the information provided in this submission, the *Mesh GPS* device is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 1 5 2010

Surgical Structure, Ltd.
% Push-Med LLC
Ms. Shoshana Friedman
1914 J.N. Pease Place
Charlotte, North Carolina 28262

Re: K092726
Trade/Device Name: Mesh GPS™ Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OQL, GCJ
Dated: February 24, 2010
Received: February 25, 2010

Dear Ms. Friedman:

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" (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 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

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092726
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Indications for Use Statement

510(k) Number (if known):_____

Device Name: *Mesh GPS*

Indications For Use: The *Mesh GPS* device is intended to be used to facilitate the delivery of soft tissue prosthetics during the laparoscopic repair of hernia.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(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)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092726