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Section E

Traditional 510(k) - Summary

In Accordance with 21 CFR Section 807.92 Power Medical Interventions, Inc., is submitting the following 510(k) Summary:

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: February 13, 2004

2) Name of Device:

Trade Name: SurgASSIST®
Straight Linear 4 Row No Knife DLUs
with Reloads

Common Name: Linear Staplers with Implantable Staples and Reloads

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

a. SurgASSIST® Straight Linear Stapler Digital Loading Units® with Reloads and Straight Linear 4 Row No Knife Digital Loading Units® with Reloads, Power Medical Interventions, Inc., New Hope, PA. REF SLS55B, SLSR55B, SLS55G, SLSR55G, SLS55B4 and SLSR55B4 (K030653).

4) Device Description:

The devices described here are reloadable Straight Linear 4 Row No Knife Digital Loading Units® (DLUs) with Reloads for single patient use. The SLS55B4 DLUs are designed to place two, double-staggered rows of titanium staples in various types of tissues. The SLS55B4 DLUs are used to close otomies and other common and uncommon openings by applying staples through the tissue and forming the staples to a controlled closed condition to secure the layers of tissue together.

5) Device Modification

The Straight Linear 4 Row No Knife Digital Loading Units® are identical to the predicate devices (K030653). The only changes are in the "Indications For Use" statement. The specific change is to include the application of the device for open occlusion of the heart's left atrial appendage.

6) Indications For Use

The SurgASSIST® Straight Linear 4 Row No Knife Digital Loading Units® with Reloads have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, creation of anastomoses, for open occlusion of the heart's left atrial appendage.

7) Comparison to Predicate Devices

The Straight Linear 4 Row No Knife Digital Loading Units® with Reloads are identical to the previously cleared predicate Straight Linear 4 Row No Knife Digital Loading Units® with Reloads (K030653). We have expanded the Indications For Use, but the fundamental scientific technology is identical. Please refer to Section J for predicate comparison chart.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2004

Ms. Barbara Whitman
Regulatory Affairs Manager
Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, Pennsylvania 18938-1364

Re: K040398
Trade/Device Name: SurgASSIST® Straight Linear 4 Row No Knife Digital Loading Units® with Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: February 13, 2004
Received: February 17, 2004

Dear Ms. Whitman:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040398

Section D

Indications for Use

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) Number (if known):

Device Name: SurgASSIST®
Straight Linear 4 Row No Knife
Digital Loading Units® with Reloads

Indications For Use:

The SurgASSIST® Straight Linear 4 Row No Knife Digital Loading Units® with Reloads have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, creation of anastomoses, for open occlusion of the heart's left atrial appendage.

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)

Miriam C. Provost

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

510(k) Number K040398