K040720 Page 1/2

JUN 0 3 2004

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: March 17, 2004

2) Name of Device:

Trade Name: SurgASSIST®
Computer Mediated Linear Cutter (CMLC)
Digital Loading Units® (DLUs)
30 mm, 55 mm, 75 mm

Common Name: Linear Staplers with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

a. SurgASSIST® Straight Linear Cutter Digital Loading Units® with Reloads, Power Medical Interventions, Inc., New Hope, PA. REF SLC55B, SLCR55B, SLC55G, SLCR55G, SLC30B, SLCR30B, SLC30G, SLCR30G (K020719).

b. 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, SLSR55B4 (K040398).

c. USSC Auto Suture TA & GIA Staplers, United States Surgical, Norwalk, CT. REF TA, GIA (K032696).

4) Device Description:

The devices described here are reusable CMLC DLUs used in conjunction with a variety of Reloads, which were previously cleared to market under K020719 and K030653. The DLUs are designed to be cleaned and sterilized for multi-patient use.

5) Device Modification

The CMLC DLUs have identical technological features as the predicate devices (K020719). The CMLC DLUs underwent material changes in order for the DLUs to withstand multiple cleaning and autoclave cycles for the purpose of multi-patient use. The average anvil clamp force was increased from 50 lbs. on the predicate device to 100 lbs. on the Computer Mediated Linear Cutter DLUs.

6) Indications For Use

The SurgASSIST® Computer Mediated Linear Cutter Digital Loading Units® have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, creation of anastomoses, and for open occlusion of the heart's left atrial appendage.

7) Comparison to Predicate Devices

The CMLC DLUs have the same function as the previously cleared predicate Straight Linear Cutter Digital Loading Units® with Reloads (K020719). Material changes in the DLUs allow for cleaning, sterilizing, and multi-patient use. The average anvil clamp force was increased in the CMLC DLUs. For further details, please refer to Section J for predicate comparison chart.

The CMLC DLUs Indications For Use statement is identical to that which appears in the following two predicate devices, K040398 and K032696.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2004

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

Re: K040720
Trade/Device Name: SurgASSIST® Computer Mediated Linear Cutter Digital Loading Units®
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 18, 2004
Received: March 19, 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

Section D K040720

Indications for Use

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) Number (if known):

Device Name: SurgASSIST®
Computer Mediated Linear Cutter
Digital Loading Units®

Indications For Use:

The SurgASSIST® Computer Mediated Linear Cutter Digital Loading Units® have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, creation of anastomoses, and 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

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510(k) Number K040720