Section E
Special 510(k) – Corrective Action Being Effected
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: January 6, 2004

2) Name of Device:

Trade Name: SurgASSIST®
Circular Stapler DLUs – 29 mm

Common Name: Circular Stapler with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

SurgASSIST® Circular Stapler Digital Loading Units®, (21 mm, 25 mm, 29 mm, 33 mm), with Titanium Implantable Staple, Power Medical Interventions, Inc., New Hope, PA. REF CS21, CS25, CS29, CS33 (K003277 and K032701).

4) Device Description:

The SurgASSIST® Circular Stapler Digital Loading Units® (DLUs) offer computer mediated steering and stapling. The DLUs contain implantable, titanium staples and integral cutting blades. The DLUs are used to anastomose tubular structures by applying a double staggered

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circular row of staples through the tissue. The staples form to controlled closed conditions to secure the layers of tissue together. The DLUs also cut away the excess tissue at a controlled diameter inside the ring of staples. The Circular Stapler DLUs are available in the following four sizes: 21 mm, 25 mm, 29 mm, and 33 mm. The DLU is supplied sterile and ready for use upon removal from its packaging. The purpose of this submission is to clear the modifications to the 29 mm Circular Stapler DLU only.

5) Device Modification

Modifications were made to the predicate SurgASSIST® Circular Stapler Digital Loading Units® - 29 mm (originally cleared under K003277) to address the root cause of the voluntary recall, which was a potential for latching mechanism failure. In order to minimize the risk of latching mechanism failure, addition of vent holes, heptagon design added to the trocar tip, modification to the housing, coating of the lead screws, modification of anvil stems and an addition of a latch finger spline were the design changes made to improve engagement of the latch fingers. Further details of this modification can be found in Section H of this submission, under the "Device Modification" heading.

6) Indications For Use

The SurgASSIST® Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

7) Comparison to Predicate Devices

The modified Circular Stapler Digital Loading Unit® - 29 mm maintains the same fundamental scientific technology as the predicate device. The primary change to the device is the increased strength and reliability of the latching mechanism. Details of the modifications can be found in Section H of this submission, under the "Device Modification" heading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

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

Re: K040024
Trade/Device Name: SurgAssist® Circular Stapler Digital Loading Units® - 29 mm
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: January 6, 2004
Received: January 7, 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

Indications for Use

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) Number (if known): K040024

Device Name: SurgASSIST®
Circular Stapler Digital Loading Units® - 29 mm

Indications For Use:

The SurgASSIST® Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

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 K040024