SECTION E - Special 510(k) Summary

SEP – 1 2006

In Accordance with 21 CFR Section 807.92 Power Medical Interventions® is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
2021 Cabot Blvd.
Langhorne, PA 19047
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: June 8, 2006

2) Name of Device:

Trade Name: Power Circular Stapler Digital Loading Unit®

Common Name: Circular Staplers with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

SurgASSIST® Circular Stapler Digital Loading Units®, Power Medical Interventions, Inc., K003277.

4) Device Description

Power Circular Stapler Digital Loading Units® are single use, disposable, surgical stapling devices designed for creating a circular anastomosis between two tubular structures and/or tissue layers.

5) Device Modification

The Power Circular Stapler Digital Loading Units® cut and staple identically to the predicate device, Circular Stapler Digital Loading Units® (K003277). The rigid length of the Power Circular Stapler Digital Loading Units® have been reduced by relocating portions of the gearing into the proximal end of the device, while redesigning the anvil clamping mechanism. There are Power

Circular Staplers which incorporate a retractable dilator that is attached to the distal end of the DLU. The dilator provides a tapered leading edge, which eases DLU insertion.

6) Indications For Use

The Power 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 Power Circular Stapler Digital Loading Units® have the same indications for use and the same functionality as the previously cleared predicate Circular Stapler Digital Loading Units® (K003277). Both the Power Circular Stapler Digital Loading Units® and the Circular Stapler Digital Loading Units® deliver two staggered rows of titanium staples on each side of a circular transection. For further details, please see the Predicate Comparison Chart in Section J of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2006

Power Medical Interventions
% Ms. Barbara J. Whitman
Regulatory Affairs Manager
2021 Cabot Boulevard West
Langhorne, Pennsylvania 19047

Re: K061649
Trade/Device Name: Power Circular Stapler Digital Loading Units®
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 7, 2006
Received: August 8, 2006

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.

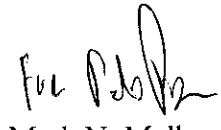
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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): K061649

Device Name: Power Circular Stapler Digital Loading Units®

Indications for Use:

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

Note: The Indications For Use for the Power Circular Stapler Digital Loading Units® are identical to that of the predicate device, Circular Stapler Digital Loading Units®, which were cleared to market via K003277.

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)

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

510(k) Number K061649