K052910 page 1/2

NOV -7 2005

SECTION E - Special 510(k) Summary

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: October 14, 2005

2) Name of Device:

Trade Name: Power Right Angle Linear Cutter Digital Loading Unit®

Common Name: Linear Staplers with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

SurgASSIST® Right Angle Linear Cutter Digital Loading Units®, Power Medical Interventions, Inc., K012809.

SurgASSIST® Right Angle Linear Cutter Digital Loading Units® with Reloads, Power Medical Interventions, Inc., K021701.

4) Device Description

The device described here is a Power Right Angle Linear Cutter Digital Loading Unit® used in gastrointestinal, gynecological, thoracic, bariatric and other surgeries for resections, transactions and the creation of anastomoses.

5) Device Modification

The Power Right Angle Linear Cutter Digital Loading Unit® cuts and staples identically to the predicate devices (K021701 and K012809). The Power Right Angle Linear Cutter Digital Loading Unit® was modified to enhance ease of

use. This new design enables the anvil to swivel 90 degrees once the DLU is opened beyond 16 mm, allowing the user to work in confined anatomical areas.

6) Indications For Use

The Power Right Angle Linear Cutter Digital Loading Units® have applications in gastrointestinal, gynecological, and general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

7) Comparison to Predicate Devices

The Power Right Angle Linear Cutter Digital Loading Units® have the same indications for use and the same functions as the previously cleared predicate Right Angle Linear Cutter Digital Loading Units® (K012089 and K021701). Both the Power Right Angle Linear Cutter Digital Loading Units® and the Right Angle Linear Cutter Digital Loading Units® deliver two staggered rows of titanium staples on each side of a 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

NOV - 7 2005

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

Re: K052910
Trade/Device Name: Power Right Angle Linear Cutter Digital Loading Units®
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: October 14, 2005
Received: October 17, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D – Statement of Indications for Use

Indications for Use

510(k) Number (if known): K052910

Device Name: Power Right Angle Linear Cutter Digital Loading Units®

Indications For Use:

The Power Right Angle Linear Cutter Digital Loading Units® have applications in gastrointestinal, gynecological, and general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

K052910

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K052910