K063075

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:

NOV - 2 2006

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 4, 2006

2) Name of Device:

Trade Name: Natural Orifice Linear Cutter Digital Loading Units ®

Common Name: Linear Staplers with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

SurgASSIST® Power Linear Cutter Reusable Digital Loading Unit®, Power Medical Interventions, Inc., K052415.

4) Device Description

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

5) Device Modification

The Natural Orifice Linear Cutter Digital Loading Unit® cuts and staples identically to the predicate device Power Linear Cutter Digital Loading Unit® (K052415). The modifications include the following: 2-button handle instead of 3-button handle; autoclavable flexible shaft replaces the rigid stainless steel shaft; and anvil material changed from tungsten to stainless steel.

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6) Indications For Use

The Natural Orifice 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 Natural Orifice Linear Cutter Digital Loading Unist® have the same indications for use and the same functions as the previously cleared predicate Power Linear Cutter Reusable Digital Loading Units® with Reloads *(K052415). Both the Natural Orifice Linear Cutter Digital Loading Units® and the Power Linear Cutter Reusable Digital Loading Units® with Reloads 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 - 2 2006

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

Re: K063075
Trade/Device Name: Natural Orifice Linear Cutter Digital Loading Units®
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: October 4, 2006
Received: October 6, 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

SECTION D – Statement of Indications for Use

Indications for Use

510(k) Number (if known): Subject of this notification K063075

Device Name: Natural Orifice Linear Cutter Digital Loading Units®

Indications for Use:

The Natural Orifice Linear Cutter 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, and for open occlusion of the heart's left atrial appendage.

Note: The Indications For Use for the Natural Orifice Linear Cutter Digital Loading Units® are identical to that of the predicate device, Power Linear Cutter Digital Loading Units®, which were cleared to market via K052415.

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)

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

510(k) Number K063075