K083527

DEC 18 2008

Section E

Special 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.
2021 Cabot Blvd.
Langhorne, PA 19047
Ph: 267-775-8151
Fax: 267-775-8123

Applicant: Barbara J. Whitman

Date of Notification: November 26, 2008

2) Name of Device:

Trade Name: Intelligent Articulating Endoscopic Linear Cutters Reverse with Reloads

Common Name: Linear Staplers with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Device:

Intelligent Articulating Endoscopic Linear Cutters with Reloads, Power Medical Interventions, Inc., Langhorne, PA. REF i45, i45S, i60, i60S (K071708).

4) Device Description:

5) Device Modification

The Intelligent Articulating Endoscopic Linear Cutter Reverse with Reloads has identical technological features as the predicate device, i45/i60 (K071708). The modification made to the device was that the pivot point for the jaws was translated distally, which enables the device to open in Reverse. Both the subject device and the predicate device deliver stapling/cutting action to create anastomoses.

6) Indications For Use

The Intelligent Articulating Endoscopic Linear Cutters Reverse with Reloads have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

7) Comparison to Predicate Devices

The Intelligent Articulating Endoscopic Linear Cutters Reverse functions the same as the predicate device, i45/i60 (K071708). The electronics, power configuration, and internal gearing & transmission are common to both the Intelligent Articulating Endoscopic Linear Cutters Reverse and i60/i45. The difference is that the pivot point for the stapling jaws was translated distally in order to enable the device to open in reverse. The shafts on both the subject device, Intelligent Articulating Endoscopic Linear Cutters Reverse, and the predicate device, i45/i60, are both rigid. Both devices are powered mechanically by rotational energy. In both the predicate and the subject device, a clamp shaft drives a clamp screw, which causes the anvil to close and compress tissue. The same is true for firing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

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

Re: K083527
Trade/Device Name: Intelligent Articulating Endoscopic Linear Cutter Reverse with Reloads
Regulation Number: 21 CFR 878.4750
Regulatory Class: II
Product Code: GDW
Dated: November 26, 2008
Received: November 28, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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

Enclosure

Section D

Indications for Use

510(k) Number (if known): K083527

Device Name: Intelligent Articulating Endoscopic Linear Cutter Reverse with Reloads

Indications For Use:

The Intelligent Articulating Endoscopic Linear Cutters Reverse with Reloads have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of 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)

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

510(k) Number K083527