K081826

JUL 25 2008

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: June 26, 2008

2) Name of Device:

Trade Name: i30V, i45V, i60V, iR30V, iR45V, iR60V, i30SV, i45SV, i60SV

Common Name: Intelligent Articulating and Straight Endoscopic Linear Cutters – Vascular with Reloads

Regulation Name: Staple, Implantable

Product Code: GDW

3) Predicate Devices:

- i45, i45S, i60, i60S, Power Medical Interventions, Inc., Langhorne, PA. (K071708)
- Right Angle Linear Cutter DLUs, 30 mm, 45 mm and 60 mm Vascular with Reloads, Power Medical Interventions, Inc., Langhorne, PA. (K022313)

4) Device Description:

The Intelligent Articulating and Straight Endoscopic Linear Cutters – Vascular with Reloads are reusable, articulating and non-articulating, handheld vascular surgical staplers. The devices are supplied non-sterile and must be cleaned and sterilized prior to use. The device creates a linear transection with three staggered rows of titanium staples on each side of the cutting blade.

5) Device Modification:

Intelligent Articulating and Straight Endoscopic Linear Cutters – Vascular with Reloads are identical in function as the predicate device i45, i45S, i60, i60S previously cleared under (K071708), except that an additional row of staggered staple pockets have been added to the anvil. This modification along with the Vascular Reloads creates a linear transection with three staggered rows of formed titanium staples on each side of the cutting blade. This is identical to the predicate Right Angle Linear Cutter DLU 30 mm, 45 mm, & 60 mm Vascular with Reloads previously cleared under (K022313). The software has been modified to properly operate the modified devices with the Reloads.

6) Indications For Use:

The Intelligent Articulating and Straight Endoscopic Linear Cutters – Vascular with Reloads have applications for general and endoscopic surgery including multiple open or minimally invasive general, gynecological, urologic (including radical prostatectomy) thoracic, and pediatric surgical procedures for transaction, resection, and/or creation of anastomoses. They can be used with staple line or tissue buttressing material such as bovine pericardium.

7) Comparison to Predicated Devices:

The Intelligent Articulating Endoscopic Linear Cutters – Vascular with Reloads i30V, i45V, i60V (subject of this notification) and the predicate device i45/i60 (K071708) are reusable articulating handheld endoscopic linear cutters. The Intelligent Straight Endoscopic Linear Cutters – Vascular with Reloads i30SV, i45SV, i60SV and the predicate device i45S/i60S (K071708) are reusable, non-articulating handheld endoscopic linear cutters. The modified devices and the predicate devices are all battery powered with the control switches and rocker switches in the handle

The Intelligent Articulating and Straight Endoscopic Linear Cutters – Vascular with Reloads have the exact Indications For Use as the predicate device, Right Angle Linear Cutter Digital Loading Unit 30mm, 45mm 60mm with Vascular with Reloads (K022313).

Please see the Predicate Device Comparison Chart in section H of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 2 5 2008

Re: K081826
Trade/Device Name: i30V, i45V, i60V, iR30V, iR45V, iR60V, i30SV, i45SV, i60SV
Regulation Number: 21 CFR 878.4750
Device Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: June 26, 2008
Received: June 27, 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
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

Device Name: i30V, i45V, i60V, iR30V, iR45V, iR60V, i30SV, i45SV, i60SV

Indications for Use:

The Intelligent Articulating and Straight Endoscopic Linear Cutters – Vascular with Reloads have applications for general and endoscopic surgery including multiple open or minimally invasive general, gynecological, urologic (including radical prostatectomy) thoracic, and pediatric surgical procedures for transaction, resection, and/or creation of anastomoses. They can be used with staple line or tissue buttressing material such as bovine pericardium.

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 K081798

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