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
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DEC 07 2007

Applicant: Barbara J. Whitman

Date of Notification: November 7, 2007

2) Name of Device:

Trade Name: iDriveS, iDriveC, iDriveF with Vascular Indications

Common Name: Intelligent Delivery System, Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

- i45, i45S, i60, i60S, Power Medical Interventions, Inc., Langhorne, PA. (K071708)
- Power Extenders, Power Medical Interventions, Inc., Langhorne, PA. (K063746)
- Right Angle Linear Cutter DLUs, 30 mm, 45 mm and 60 mm Vascular, Power Medical Interventions, Inc., Langhorne, PA. (K022313)

4) Device Description

The iDrive is a reusable, hand-held medical device that is used to operate various SurgASSIST® Digital Loading Units® (DLUs), all of which were previously cleared to market. The iDrive consists of a handpiece with integrated controls that operate the DLUs.

5) Device Modification

The iDrive functions identically to the predicate devices i45, i45S, i60, i60S (K071708) and the Power Extenders (K063746). The i45, i45S, i60, i60S was modified in order to enable the firing of multiple DLUs from the battery

powered, hand-held device. The distal connector on the iDrive is identical to that found on the predicate device, Power Extender. It is this connector, which enables the iDrive to be compatible with multiple DLUs, including the predicate vascular DLUs (K022313).

6) Indications For Use

The iDrive is capable of firing multiple DLUs, which were previously cleared to market. The DLUs are fired by the iDrive, but function as the component of the device responsible for delivering the implantable staple. As such, the Indications for Use of each vascular device are included below:

The **iDriveS/iDriveC/ iDriveF**, when used with compatible Vascular Digital Loading Units®, has applications for general and endoscopic surgery including multiple open and minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures for resection, transection, and/or creation of anastomoses. They can be used with staple line or buttressing material such as bovine pericardium.

7) Comparison to Predicate Devices

The iDrive with Vascular Indications functions identically to the predicate devices i45, i45S, i60, i60S (K071708), the Power Extenders (K063746), and the Right Angle Linear Cutter Vascular DLUs (K022313), as it enables the user to control the battery powered, hand-held device with buttons and rocker switches, which are then able to fire multiple DLUs, including Vascular ones. The predicate device, Power Extender, was able to fire multiple DLUs, but was tethered to the PC100 via a FlexShaft. The iDrive is capable of firing the same DLUs, which were fired by the Power Extender. However, the iDrive, is also similar to the i45, i45S, i60, i60S, as it is also an untethered, battery powered, hand-held device, capable of firing multiple DLUs. 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

DEC 0 7 2007

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

Re: K073148
Trade/Device Name: iDrive with Vascular Indications
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 07, 2007
Received: November 08, 2007

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

K073148

SECTION D – Statement of Indications for Use

Indications for Use

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

Device Name: iDrive with Vascular Indications

Indications for Use:

The **iDriveS/iDriveC/ iDriveF**, when used with compatible Vascular Digital Loading Units®, have applications for general and endoscopic surgery including multiple open and minimally invasive general, gynecological, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures for resection, transection, and/or creation of anastomoses. They can be used with staple line or 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)

(Division Sign-Off) Division of CDRH, Office of Device Evaluation (ODE)

Division of [illegible]
and Neurological [illegible]

510(k) Number K073148 K070000015