K071708
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Section E

SEP 27 2007

Traditional 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. West
Langhorne, PA 19047 USA
Ph: 267-775-8151
Fax: 267-775-8123

Applicant: Barbara J. Whitman

Date of Notification: June 19, 2007

2) Name of Device:

Trade Name: i45, i45S, i60, i60S

Common Name: Linear Staplers with Implantable Staples

Classification: Staple, Implantable, GDW

3) Predicate Devices:

a) SurgASSIST® System with Circular Stapler Digital Loading Units®. Power Medical Interventions, Inc., Langhorne, PA. (K003277). REF PC100; RCW100; FS14, CS21, CS25, CS29, CS33.

b) FlexShaft II, Power Medical Interventions, Inc., Langhorne, PA. (K021249). REF FS214

c) SurgASSIST® Computer Mediated Linear Cutter Digital Loading Units®. Power Medical Interventions, Inc., Langhorne, PA. (K040720). REF CMLC30, CMLC55, CMLC75.

4) Device Description:

The devices described here are reusable i45, i45S, i60, i60S used in conjunction with a variety of Reloads, which were previously cleared to market under K052415. The i45, i45S, i60, i60S are designed to be cleaned and sterilized for multi-patient use.

5) Device Modification:

The i45, i45S, i60, i60S have identical technological features as the predicate devices (K003277, K021249, and K040720). The i45, i45S, i60, i60S is an integrated stapler that articulates left and right. In addition to motors for stapling and cutting, and articulation, the proximal housing holds the battery and electronics enabling untethered use. Device control is managed with buttons and rocker switches on the proximal housing. The device will be steam sterilized. All product patient contact materials adhere to industry standards.

The predicate devices for the power, transmission, and control aspects are the PC100, previously cleared to market via K003277 and the FS214, previously cleared to market via K021249. In the predicate device, AC power was converted to 24Vdc driving DC motors. In the subject device, a battery rated at 14.8Vdc powers two DC motors directly. In the predicate device, transmission of rotational power was accomplished through the use of a FlexShaft. In the subject device, the rotational power is transmitted through a rigid shaft. In the predicate device, control for articulation and stapling was achieved through a Remote Control Unit plugged into the Power Console. In the subject device, control is integrated into the handpiece.

The predicate device for the stapling and cutting aspects is the Computer Mediated Linear Cutter, previously cleared to market via K040720. Both the predicate and the subject devices provided 4 rows of staples with a transection in the middle. Both are steam sterilizable, multi-patient use devices.

6) Indications For Use (identical to those in the predicate CMLC DLU, K040720) -

The i45, i45S, i60, i60S have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal, 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 i45, i45S, i60, i60S have the same function as the previously cleared predicate devices. The subject device provides stapling and cutting, similar to that of the CMLC, but is no longer tethered to the PC100.

The Indications For Use statement is identical to that which appears in the CMLC predicate device (K040720).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Power Medical Interventions, Inc.
% Peter Shearstone
Sr. VP. Regulatory/Quality Assurance
2021 Cabot Boulevard West
Langhorne, Pennsylvania 19047

SEP 27 2007

Re: K071708
Trade/Device Name: i45/i45s/i60/i60s
Regulation Number: 21 CFR 878.4750
Regulation Name: Linear Stapler with Implantable Staples
Regulatory Class: II
Product Code: GDW
Dated: September 13, 2007
Received: September 13, 2007

Dear Mr. Shearstone:

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.

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

Indications for Use

510(k) Number (if known): K071708

Device Name: i45, i45S, i60, i60S

Indications for Use:

The i45, i45s, i60, i60s have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal, thoracic surgical procedures for resection, transection, creation of anastomoses, and for open occlusion of the heart's left atrial appendage.

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

510(k) Number K071708

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)