Special 510(k) Device Modification
PREMARKET NOTIFICATION
SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST™ Right Angle Linear Cutter DLU with Reloads, 30mm, 45mm, 60mm

In Accordance with 21 CFR section 807.92 Power Medical Interventions, Inc., is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
215-862-4450 Ph
215-862-1009 Fax

Applicant: Barbara J. Whitman

Date of Notification: May 20, 2002

2) Name of Device:

Trade Name: SurgASSIST™
Right Angle Linear Cutter DLU
with Reloads

Common Name: Linear Cutter with Implantable Staples
and Reloads

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

a) SurgASSIST™ System with Right Angle Linear Cutter Digital Loading Unit™ with Titanium Implantable Staple, Power Medical Interventions, Inc., New Hope, PA. REF RALC45. (K012809).

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b) EZ45 Endoscopic Linear Cutter/Stapler Reloads. Ethicon Endo-Surgery, Inc., Cincinnati, Ohio. REF ET45B (K980815).

4) Device Description:
The devices described here are reloadable Right Angle Linear Cutter DLUs for single patient use. Both the 30mm RALC and the 45mm RALC can be passed through surgical tubing with an inside diameter of 3.1". The 60mm RALC can be passed through surgical tubing with an inside diameter of 4.1". They are all supplied pre-sterilized and ready for use upon removal from their packaging.

The 30mm DLU can be used with only the 30mm reloadable cartridge.

The 45mm DLU can be used with only the 45mm reloadable cartridge.

The 60mm DLU can be used with only the 60mm reloadable cartridge.

During the Design Input stage of the Right Angle Linear Cutter, it was determined that the product would evolve into a reloadable device. Features that were incorporated into the non reloadable were designed in such a fashion that the components would yield a reloadable component.

These features designed into a non reloadable version that would be useful in a reloadable version include the latch that would allow the cartridge to be removed and the tongs of the cartridge cap that would secure the reload in position but be capable of being removed as well. The design that features the reloadable cartridges maintain much of the features of the non reloadable but with modest modifications.

Each DLU contains a staple-forming anvil. The anvil acts with the staple cartridge to compress and position layers of tissue in readiness for stapling and cutting. At the same time, the anvil provides support and a means for correctly forming staples while they are closed sequentially along the tissue, followed by the cutting blade. The 30mm, 45mm and 60mm DLUs are perpendicular to the FlexShaft, forming an extension to the Flex Shaft, to which they are connected.

A loaded DLU is used to anastomose tubular structures by applying staples through the tissue and forming the staples to a controlled closed condition to secure the layers of tissue together. It also severs the tubular structure.

Right Angle Linear Cutter DLU Reloads contain staples, a cutting blade, and the means to simultaneously force staples toward the anvil. The cutting blade is advanced in conjunction with the staple pushers so that tissue is simultaneously stapled and cut. The DLUs are attached to the end of the FlexShaft assembly that contains a pair of flexible rotary drive shafts within an overall flexible shaft called the FlexShaft, hereafter referred to as the FS. The other end of the FS is connected to a Power Console (the PC), which applies mechanical power to the drive shafts. DLUs

have all functions powered by the PC. The FS has a short steerable section at the distal end (near the attached DLU) so that the angle of attack (attitude) of the DLU can be adjusted by the surgeon to optimize patient accessibility.

The surgeon operates a DLU via a hand held electronic Remote Control Unit (RCU).

The DLUs have quick attach and release means for coupling to the FS. No tools are required. DLUs are pushed onto the FS end, snapping and locking into place. To remove a DLU from the FS, a sleeve on the DLU at the junction with the FS is rotated by hand.

DLU designs shall allow for attachment of their corresponding Reloads, but shall inhibit attachment of incompatible cartridges. Each Reload has an integral electronic memory module. This identifies the type and size of the Reload being used.

5) Indications For Use - The Right Angle Linear Cutter DLU with Reloads, 30mm, 45mm, 60mm will have substantially equivalent Indications For Use as the predicate device K012809.

The SurgASSIST™ Right Angle Linear Cutter DLU with Reloads has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

6) Comparison to Predicate Devices

The following table compares the subject Right Angle Linear Cutter DLU with Reloads to the previously cleared predicate Right Angle Linear Cutter DLU (K012809) device and the Ethicon Endopath EZ45 Endoscopic Linear Cutter with Reloads (K980815):

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Right Angle Linear Cutter DLU Product Features Comparison Chart

Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads 30mm, 45mm, 60mm	Predicate SurgASSIST™ Right Angle Linear Cutter DLU 45mm	Predicate Endopath EZ45 Endoscopic Linear Cutter
Name	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads	SurgASSIST™ Right Angle Linear Cutter DLU	Endopath EZ45 Endoscopic Linear Cutter
Manufacturer of Record	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.	Ethicon Endo-Surgery, Inc.
Contract Manufacturer	Lacey Manufacturing Bridgeport, CT	Lacey Manufacturing Bridgeport, CT	Ethicon Endo-Surgery, Inc.
510(k) Clearance Numbers	Subject of this Notification	K012809	K980815
Product Codes	RALC30, RALC45, RALC60 RALCR30, RALCR45, RALCR60	RALC45	EZ45
Intended use	Has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.	Has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.	Application in gastroenterology for transection, resection, and/or creation of anastomoses and can be used in multiple open or minimally invasive surgical procedures, including radical prostatectomy, and can be used with staple line or tissue buttressing materials, such as bovine pericardium.

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Right Angle Linear Cutter DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads 30mm, 45mm, 60mm	Predicate SurgASSIST™ Right Angle Linear Cutter DLU 45mm	Predicate Endopath EZ45 Endoscopic Linear Cutter
FDA Class (System)	II	II	II
Physical Characteristics			
Number of Staples	30mm - 22 staples **45mm** - 32 staples 60mm - 46 staples	**45mm** - 32 staples	44
Rows of Staples	30mm - 4 rows **45mm** - 4 rows 60mm - 4 rows	**45mm** - 4 rows	4 rows
Staple Crown Dimension	30mm - 3.5mm **45mm** - 3.5mm 60mm - 3.5mm	**45mm** - 3.5mm	3.0
Staple Leg Dimension	30mm - 4.4mm **45mm** - 4.4mm 60mm - 4.4mm	**45mm** - 4.4mm	4.1
Staple Thickness	30mm - 0.23mm **45mm** - 0.23mm 60mm - 0.23mm	**45mm** - 0.23mm	.20
Staple Closed Range	30mm - 1.2 / 2.0mm **45mm** - 1.2 / 2.0mm 60mm - 1.2 / 2.0mm	**45mm** - 1.2 / 2.0mm	2.0
DLU Internal Power	None	None	None
Digital Information	Memory module containing digital data for identification, etc.	Memory module containing digital data for identification, etc.	None
How Supplied	Sterile - Single Patient Use	Sterile - Single Patient Use	Sterile - Single Patient Use

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Right Angle Linear Cutter DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads 30mm, 45mm, 60mm	Predicate SurgASSIST™ Right Angle Linear Cutter DLU 45mm	Predicate Endopath EZ45 Endoscopic Linear Cutter
Method of Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Irradiation
Packaging			
Digital Loading Unit™	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid
Reloads	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid

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Right Angle Linear Cutter DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Right Angle Linear Cutter DLU with Reloads 30mm, 45mm, 60mm	Predicate SurgASSIST™ Right Angle Linear Cutter DLU 45mm	Predicate Endopath EZ45 Endoscopic Linear Cutter
Method of Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)
Packaging			
Digital Loading Unit™	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid
Reloads	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2002

Ms. Barbara J. Whitman
Regulatory Affairs Specialist
Powêr Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938

Re: K021701
Trade/Device Name: SurgASSIST™
Right Angle Linear Cutter
Digital Loading Unit™
with Reloads, 30mm, 45mm, 60mm
Regulation Number: 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: May 20, 2002
Received: May 23, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) No. K Ø21701

Device Name: *SurgASSIST™*
Right Angle Linear Cutter
Digital Loading Unit™
with Reloads, 30mm, 45mm, 60mm

INDICATIONS FOR USE:

The SurgASSIST™ System Right Angle Linear Cutter Digital Loading Unit™ (DLU) with Reloads has applications in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X OR Over-The-Counter Use _____
Per 21CFR §801.109

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021701