MAR 3 1 2003

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

SurgASSIST ***Straight Linear Stapler and Straight Linear 4 Row No Knife Digital Loading Units® with Reloads***

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
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: February 28, 2003

2) Name of Device:

Trade Name: SurgASSIST™
Straight Linear Stapler DLU with Reloads
and
Straight Linear 4 Row No Knife DLU
with Reloads

Common Name: Linear Stapler with Implantable Staples and Reloads

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

A. SurgASSIST™ System with Straight Linear Cutter Digital Loading Units®, 55mm and 30mm with Blue and Green Reloads, with Titanium Implantable Staple, Power Medical Interventions, Inc., New Hope, PA. REF SLC55B, SLC55G, SLCR55B, SLCR55G, SLC30B, SLC30G, SLCR30B, SLCR30G. (K020719).

B. Endopath ETS Flex45 No-Knife Articulating Linear Stapler, Ethicon Endo-Surgery, Inc., Cincinnati, OH. REF NAB, NAG. (K020779).

4) Device Description:

The devices described here are reloadable Straight Linear Stapler and Straight Linear 4 Row No Knife Digital Loading Units® (DLUs) with Reloads for single patient use. All have a maximum diameter of .596" and can be used within a 15 mm cannula. The DLUs are supplied pre-sterilized and ready for use upon removal from their packaging. Reloadable stapling and cutting cartridges are referred to as "Reloads".

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, when included. The 15 mm diameter DLUs are axial to the FlexShaft, forming a straight extension to the FlexShaft, to which they are connected.

Loaded Straight Linear Stapler and Straight Linear 4 Row No Knife DLUs are used to close otomies and other common and uncommon openings by applying staples through the tissue and forming the staples to a controlled closed condition to secure the layers of tissue together. Straight Linear Stapler and Straight Linear 4 Row No Knife Reloads contain staples and the means to sequentially force staples toward the anvil. The cutting blade, when included, is advanced immediately behind the staple pushers so that tissue is sequentially stapled and then cut, proceeding from one end of the cartridge to the other.

Straight Linear Stapler DLUs, 55 mm with Blue and Green Reloads have 2 staggered rows of staples on one side of the cutter, coded Blue (1.2 mm) for normal tissue and Green (2.0 mm) for thick tissue. DLUs are available with Blue or Green Reloads installed. Individual Blue and Green Reloads are available.

Straight Linear 4 Row No Knife DLUs, 55 mm with Gray Reloads have two, double-staggered rows of staples, coded Gray (1.2 mm) for normal tissue (same as 55 mm Blue Straight Linear Cutter without the blade). DLUs are available with Gray cartridges installed. "No Knife" distinctively labeled. Individual Gray Reloads are available.

The DLUs are attached to the end of the flexible shaft assembly that contains a pair of flexible rotary drive shafts within an overall flexible tube called the FlexShaft, hereafter referred to as FS. The other end of the FS is connected to a Power Console (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) that is plugged into the front panel of the PC.

The DLUs have quick attach and release means of 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 allow for attachment of Reloads, but will inhibit attachment of incompatible Reloads. Each Reload has an integral electronic memory module. This identifies the type and size of the Reload being used and prevents a used Reload from being refired.

5) Indications For Use

The SurgASSIST™ Straight Linear Stapler and Straight Linear 4 Row No Knife Digital Loading Units® 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.

6) Comparison to Predicate Devices

The following table compares the subject Straight Linear Stapler and Straight Linear 4 Row No Knife Digital Loading Units® with Reloads to the previously cleared predicate Straight Linear Cutter Digital Loading Units® with Reloads (K020719).

Straight Linear Stapler DLU Product Features Comparison Chart

Features & Description	SurgASSIST™ Straight Linear Stapler, 55 mm with Blue and Green Reloads and Straight Linear 4 Row No Knife Digital Loading Units® (DLUs)	**Predicate** SurgASSIST™ Straight Linear Cutter DLUs, 55 mm and 30 mm with Blue and Green Reloads	**Predicate** Ethicon Endo-Surgery, Inc. Endopath ETS Flex45 No-Knife Articulating Linear Stapler
Name	SurgASSIST™ Straight Linear Stapler DLUs, 55 mm with Blue and Green Reloads and Straight Linear 4 Row No Knife DLUs	SurgASSIST™ Straight Linear Cutter DLUs, 55 mm and 30 mm with Blue and Green Reloads	Endopath ETS Flex45 No-Knife Articulating Linear Stapler
Manufacturer of Record	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.	Ethicon Endo-Surgery, Inc
Contract Manufacturer	The MedTech Group South Plainfield, NJ	The MedTech Group South Plainfield, NJ	Ethicon Endo-Surgery, Inc
510(k) Clearance Numbers	Subject of this Notification	K020719	K020779
Product Codes	SLS55B, SLSR55B, SLS55G, SLSR55G, SLS55B4, SLSR55B4	SLC55B, SLCR55B, SLC55G, SLCR55G, SLC30B, SLCR30B, SLC30G, SLCR30G	NAB45 and NAG45
Intended use	Have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.	Have applications for general and endoscopic surgery in gastrointestinal, gynecological, general abdominal and thoracic surgical procedures for resection, transection, and creation of anastomoses.	Intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

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Straight Linear Stapler DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Straight Linear Stapler, 55 mm with Blue and Green Reloads and Straight Linear 4 Row No Knife Digital Loading Units® (DLUs)	**Predicate** SurgASSIST™ Straight Linear Cutter DLUs, 55 mm and 30 mm with Blue and Green Reloads	**Predicate** Ethicon Endo-Surgery, Inc. Endopath ETS Flex45 No-Knife Articulating Linear Stapler
Contraindications	Do not use the SurgASSIST™ Straight Linear Stapler DLU, 55mm Blue, on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily below 1.5 mm. Do not use the SurgASSIST™ Straight Linear Stapler DLU, 55 mm Green, on any tissue that requires excessive force to compress to 2.3 mm or on any tissue that compresses easily below 2.3 mm. Do not use the SurgASSIST™ Straight Linear 4 Row No Knife DLU, (Gray), on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily below 1.5 mm.	Do not use the SurgASSIST™ System Straight Linear Cutter DLU, 55 mm, 30 mm where combined tissue thickness exceeds 2.3 mm or is less than 1.0 mm.	Do not use the instrument with blue reload on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily to below 1.5 mm. Do not use on ischemic or necrotic tissue. Do not use the instruments on the aorta. Do not use any linear cutter on major vessels without making provision for proximal and distal control. Do not use the instrument on solid organs, such as liver or spleen, where attempted compression would be destructive. These instruments are not intended for use when surgical stapling is contraindicated. Do not use the instruments with green reload on any tissue that requires excessive force to compress to 2.0 mm or on any tissue that compresses easily to below 2.0 mm.
FDA Class (System)	II	II	II
Number of Staples	SLS55B, SLSR55B - 28 staples SLS55G, SLSR55G - 28 staples SLS55B4, SLSR55B4 - 56 staples	SLC55B, SLCR55B - 56 staples SLC55G, SLCR55G – 56 staples SLC30B, SLCR30B – 32 staples SLC30G, SLCR30G – 32 staples	NAB – 44 staples NAG – 44 staples

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Straight Linear Stapler DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Straight Linear Stapler, 55 mm with Blue and Green Reloads and Straight Linear 4 Row No Knife Digital Loading Units® (DLUs)	**Predicate** SurgASSIST™ Straight Linear Cutter DLUs, 55 mm and 30 mm with Blue and Green Reloads	**Predicate** Ethicon Endo-Surgery, Inc. Endopath ETS Flex45 No-Knife Articulating Linear Stapler
Rows of Staples	SLS55B, SLSR55B - 2 rows SLS55G, SLSR55G - 2 rows SLS55B4, SLSR55B4 - 4 rows	SLC55B, SLCR55B – 4 rows SLC55G, SLCR55G – 4 rows SLC30B, SLCR30B – 4 rows SLC30G, SLCR30G – 4 rows	NAB – 4 rows NAG – 4 rows
Knife/Scalpel	SLS55B, SLSR55B – scalpel included SLS55G, SLSR55G – scalpel included SLS55B4, SLSR55B4 – NO KNIFE	SLC55B, SLCR55B – scalpel included SLC55G, SLCR55G – scalpel included SLC30B, SLCR30B – scalpel included SLC30G, SLCR30G – scalpel included	NAB – NO KNIFE NAG – NO KNIFE
Staple Diameter	SLS55B, SLSR55B - .21 mm SLS55G, SLSR55G - .23 mm SLS55B4 - .21 mm	SLC55B, SLCR55B – .21 mm SLC55G, SLCR55G – .23 mm SLC30B, SLCR30B – .23 mm SLC30G, SLCR30G – .23 mm	NAB - .23 mm NAG - .23 mm
Staple Height	SLS55B, SLSR55B – 1.2 mm SLS55G, SLSR55G – 2.0 mm SLS55B4 – 1.2 mm	SLC55B, SLCR55B – 1.2 mm SLC55G, SLCR55G – 2.0 mm SLC30B, SLCR30B – 1.2 mm SLC30G, SLCR30G – 2.0 mm	NAB – 1.5 mm NAG – 2.0 mm
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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Straight Linear Stapler DLU Product Features Comparison Chart

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Features & Description	SurgASSIST™ Straight Linear Stapler, 55 mm with Blue and Green Reloads and Straight Linear 4 Row No Knife Digital Loading Units® (DLUs)	**Predicate** SurgASSIST™ Straight Linear Cutter DLUs, 55 mm and 30 mm with Blue and Green Reloads	**Predicate** Ethicon Endo-Surgery, Inc. Endopath ETS Flex45 No-Knife Articulating Linear Stapler
Method of Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Irradiation
Digital Loading Unit®	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid
Reloads	Tyvek Pouch	Tyvek Pouch	Blister Tray with Tyvek Lid

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2003

Ms. Barbara J. Whitman
Regulatory Affairs Manager
Powèr Medical Interventions, Inc.
110 Union Square Drive
New Hope, Pennsylvania 18938

Re: K030653
Trade/Device Name: SurgASSIST™ Straight Linear Stapler Digital Loading Unit® with Reloads and Straight Linear 4 Row No Knife Digital Loading Unit® with Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: February 28, 2003
Received: March 3, 2003

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 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) you may obtain. 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,

Miriam C. Provost

for 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 K030653

Device Name: *SurgASSIST™*
Straight Linear Stapler
Digital Loading Unit® with Reloads
And Straight Linear 4 Row No Knife
Digital Loading Unit® with Reloads

INDICATIONS FOR USE:

The SurgASSIST™ Straight Linear Stapler and Straight Linear 4 Row No Knife Digital Loading Units® 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.

(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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030653