Section 5
510(k) Summary

MAY 29 2008

This 510(K) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21CFR § 807.92

The assigned 510(K) number is : K 080161

Submitted by: Michael Patton
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Date Prepared: 31 October 2007

Establishment Registration Number: Patton Surgical is located at 6300 Bridgepoint Parkway, Bldg. 2, Suite 420 in Austin, Texas 78730. We are registered with the Food and Drug Administration as Establishment Number 1651380.

Classification Name: Laparoscope, General & Plastic Surgery

Common/Usual Name: Disposable Surgical Trocar/Cannula

Proprietary Name: PassPort® Optical Trocar, PassPort® Vortex Seal, PassPort® Blunt Tip Trocar, PassPort® Shielded Trocar, PassPort® Cannula Anchor

Indication for Use:

The PassPort® Optical Trocar is an access device that may be used with or without visualization that creates and maintains a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

The PassPort® Vortex Seal functions in combination with Patton Surgical's PassPort® Trocar to create and maintain a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

The PassPort® Blunt Tip Trocar is an access device that creates and maintains a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

The PassPort® Shielded Trocar is an access device that creates and maintains a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

The PassPort® Cannula Anchor functions in combination with Patton Surgical's PassPort® Trocar to create and maintain a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

Device Description:	The Candidate Devices are a single patient device to be utilized as an access port.
Substantial Equivalence Claim:	The principles of operation and technology in the candidate device are similar to other devices, which the FDA has found to be substantially equivalent as outlined below:

Product:	Endopath® Bladeless Trocar, Endopath® Blunt Tip Trocar, Endopath® Dilating Tip Trocar
Manufacturer:	Ethicon Endo-Surgery, Inc.
510(K) Number:	K032676
Substantial Equivalence Date:	10/30/03

Product:	Funnel Trocar
Manufacturer:	Patton Surgical Corp.
510(K) Number:	K992324
Substantial Equivalence Date:	08/19/99

Product:	Shielded Surgical Trocar
Manufacturer:	Ethicon Endo-Surgery, Inc.
510(K) Number:	K971475
Substantial Equivalence Date:	08/21/97

-End of summary-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

Patton Surgical Corporation
% Mr. Michael Patton
President
6300 Bridgepoint Parkway
Building 2, Suite 420
Austin, Texas 78730

Re: K080161
Trade/Device Name: PassPort® Optical Trocar, PassPort® Vortex Seal, PassPort® Blunt Tip Trocar, Passport® Shielded Trocar, PassPort® Cannula Anchor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 22, 2008
Received: May 22, 2008

Dear Mr. Patton:

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 4
Indications for Use Statement

510(K) Number: K080161

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The PassPort® Shielded Trocar is an access device that creates and maintains a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

The PassPort® Cannula Anchor functions in combination with Patton Surgical's PassPort® Shielded Trocar to create and maintain a passageway for laparoscopic instruments during a variety of laparoscopic procedures such as general, gynecologic, thoracic, and urological procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **(Per 21 CFR 801.109)**

Over-the-Counter (Optional format 1-2-96)

Neil R Ogden for mrn

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

510(k) Number K080161