Section 5. 510(k) Summary

PER 21 CFR 807.92

AUG 1 2013

510(k) Owner/Sponsor:	Stryker Endoscopy
Address:	5900 Optical Court San Jose, CA 95138
Establishment Number:	2936485
Telephone Number:	(408) 855-6377
Contact Person:	Rebecca Goldberg; Regulatory Affairs Analyst
Email Address:	rebecca.goldberg@stryker.com
Proposed Device:	**Passport® Trocars and Accessories**
Common/Usual Name:	Disposable Surgical Trocar/Cannula Accessory
Product Code:	GCJ
FDA Regulation Number:	21 CFR 876.1500 - Endoscope and accessories
Device Classification:	Class II
Predicate Device:	Passport Optical Trocar, Vortex Seal, Blunt Tip Trocar, Shielded Trocar, Cannula Anchor
Common/Usual Name:	Disposable Surgical Trocar/Cannula and Accessories
Product Code:	GCJ
FDA Regulation Number:	21 CFR 876.1500 - Endoscope and accessories
Device Classification:	Class II
Premarket Notification:	K080161

Device Description

The Passport® Trocars with pediatric indication and Accessories (herein referred to as 'proposed devices') are a family of single-use devices that serve as an access port for laparoscopic instruments during laparoscopic surgery. The two accessory devices included in the submission are the Robotic Reducer Cap and Stopcock with Rotating Male Luer. These devices are to be used with the Passport® Trocars previously cleared in K080161 (herein referred to as 'predicate devices'). The Robotic Reducer Cap can be attached to the 8.5 mm and 12 mm robotic Passport® Trocars to reduce the seal size to accommodate smaller instruments. The Stopcock with Rotating Male Luer can be attached to 3 and 5 mm Passport® Trocars that do not have built-in stopcocks in order to control flow of CO_2. The proposed devices are sterilized by ethylene oxide.

Intended Use/Indications for Use

Passport® Trocars are indicated for use as access devices that create and maintain a passageway for laparoscopic instruments during a variety of laparoscopic procedures, such as general, gynecologic, thoracic, and urological procedures in adult and adolescent (12 to 21 years of age) populations.

Technological Comparison

Passport® Trocars with pediatric indications employ the same technological characteristics as the predicate devices (K080161). The Robotic Reducer Cap and Stopcock with Rotating Male Luer employ many of the same technological characteristics as the predicate devices. The differences in the technological characteristics do not impact safety or effectiveness (See Section 12 – Substantial Equivalence).

Performance Testing

The pediatric indication expansion is the only change to the Passport® Trocars portion of the submission. Therefore this submission does not contain any performance data for the previously cleared Passport® Trocars (K08161). The accessories were tested for performance in accordance with design specifications and applicable performance standards. Biocompatibility was verified per ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and related collateral standards for patient contacting materials. Sterilization was verified per ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. Bench performance testing performed on the accessories verifies the safety and effectiveness of the devices per design specifications and acceptance criteria. Test results obtained indicate that the accessories comply with applicable performance standards.

Conclusion

The submitted information in this premarket notification is complete, and based on the indications for use, technological characteristics, performance testing and comparison to the intended use for predicate devices, Passport® Trocars and Accessories raise no new questions of safety and effectiveness and can be considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 1, 2013

Stryker Endoscopy
% Ms. Rebecca Goldberg
Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95138

Re: K130826
Trade/Device Name: Passport® Trocars and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 27, 2013
Received: July 1, 2013

Dear Ms. Goldberg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name: Passport® Trocars and Accessories

510(k) Number if known: K130826

Indications for Use:

Passport® Trocars are indicated for use as access devices that create and maintain a passageway for laparoscopic instruments during a variety of laparoscopic procedures, such as general, gynecologic, thoracic, and urological procedures, in adult and adolescent (12 to 21 years of age) populations.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K130826_____