K070712

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMISSION TYPE: Special

SUBMITTED BY:
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MAR 2 8 2007

CONTACT PERSON:
Stuart Moran
Joint Managing Director

DATE OF PREPARATION: 12th January 2007

NAME OF DEVICE: YelloPort Port Access System

CLASSIFICATION NAME: General and Plastic Surgery
(Regulation Number 21CFR 876.1500)

TRADE NAME: YelloPort

PREDICATE DEVICES: Surgical Innovations' ***PortLand Trocars*** which are cleared to market under premarket notification ***K962193***.

INDICATIONS FOR USE:
The YelloPort port access system is indicated for use in laparoscopic procedures to give access to the abdominal cavity while maintaining pneumoperitoneum.

The YelloPort port access system is also indicated for use in laparoscopic procedures to give access to the thoracic cavity.

SUMMARY STATEMENT:
In laparoscopic surgery the trocar is introduced into the cannula to accomplish cannula penetration of the abdominal wall. The cannula has a valve system at its proximal end and the trocar is removed from the cannula after the puncture of the abdominal wall. The cannula acts as a channel for the introduction of the endoscopes and instruments. Generically, trocars and cannulae are available in a range of sizes from 3mm to 13mm in diameter.

The device comprises a trocar, available with a range of tips styles, and a base. The base forms the cannula and has a removable 'cap' which retains the valve and/or lip seal. The trocar and cannula elements of the device are fully reusable and can be sterilised in pressurised steam. Valves and seals are essential accessories used in conjunction with the cannula and are available in a range of formats depending on the specific market requirements.

The YelloPort port access system is indicated for use in laparoscopic procedures to give access to the abdominal cavity while maintaining pneumoperitoneum. The YelloPort port access system is also indicated for use in laparoscopic procedures to give access to the thoracic cavity.

YelloPort is ergonomically designed to be strong and durable yet lightweight and easy to handle. Medical grade polymers ensure the main elements are fully reusable and can be autoclaved in pressurised steam. Cannulae are available with a choice of internal diameters and a range of working lengths.

Trocars are made from the finest surgical steels, hand finished to give reliable and lasting performance. The patented shielded trocar is also fully reusable and can be taken apart for ease of cleaning and maintenance. The precision ground and polished cutting tubes can be replaced economically if they become blunt or damaged.

The combination of reusable cannulae and trocars together with single-use valves / seals makes YelloPort a highly cost effective solution.

The device is manufactured from materials that comply with the requirements of ISO 10993 in terms of biocompatibility.

The YelloPort valves and seals are sterilised using a validated method of gamma irradiation, thereby providing a sterility assurance level of 10^{-6}.

The YelloPort cannulae bodies and trocars are provided non-sterile. Sterilisation instructions are provided in the instructions for use. The Surgical Innovations steam sterilisation and cleaning validation methods are based on the AAMI TIR No 12-1994, Designing, Testing and Labelling Reusable Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufactures and proves a sterility assurance level of 10^{-6}. Sterilisation validation of the steam sterilisations is based on three sterilisation cycles at one half the exposure time. The use of Bacillus sterothermophilus spore strips or inoculum is the utilised indicator.

The YelloPort Port Access System is substantially equivalent to Surgical Innovations' own PortLand Trocars, which are cleared to market under premarket notification K962193 in terms of intended use, design and use methodology, and are manufactured from similar materials.

Surgical Innovations is the manufacturer of the device and has followed design control regulations per 21 CFR § 820.30. The design controls have been in place since 1998 and have been audited by FDA on several occasions. The design of the YelloPort Port Access System was undertaken entirely within the Surgical Innovations Design Control System.

A design Risk Assessment was conducted in accordance with Surgical Innovations internal Stand Operating Procedures, ISO 9001/ISO 13485, ISO 14971 and 21 CFR § 820.30, validation and verification activities addressed in the profile. Based on the risk analysis, validation and verification activities were formally controlled and addressed by Surgical Innovations, the activities included the methods, tests used and acceptance criteria applied.

REVIEW OF PERFORMANCE DATA

Trocar Reliability and Insertion Performance

It is essential that laparoscopic trocars are sharp, are capable of ease of insertion into the abdominal wall, and are reliable if they contain moving parts. Furthermore, Surgical Innovations has undertaken a range of bench tests to determine the insertion performance and reliability of the YelloPort trocars. No known standards are available but a methodical approach has been undertaken based on extensive experience and advice from industry experts and clinicians. Many tests have been undertaken and a full list of all tests conducted has been attached. Nonetheless, tests worthy of particular note are detailed in TN100097, TN100144, TN100199 and TN100200.

Sealing Performance

It is essential that cannulae maintain pneumoperitoneum both when instruments are inserted in the cannula and when no instruments are inserted. Therefore, it is important to test both seal and valve performance at ranges from 0mmHg to a maximum of 24mmHg.

A substantial amount of test work has been undertaken and a full list of all tests conducted has been attached. Nonetheless, tests worthy of particular note are detailed in TN100131, TN100155, and TN100156.

Conclusion

It can be concluded from the above bench testing that the product performs well and is fit for purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2007

Surgical Innovations Group, plc
% Intertek Testing Services NA, Inc.
Mr. Neil E. Devine, Jr.
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K070712
Trade/Device Name: YelloPort Port Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 13, 2007
Received: March 14, 2007

Dear Mr. Devine:

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 (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

Indications for Use

510(k) Number (if known): K070712

Device Name: YelloPort Port Access System

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

510(k) Number K070712

Prescription Use ✓ AND/OR Over-The-Counter Use ____
(Part 21CFR801 Subpart D) (Part 21CFR801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)