April 29, 2019

Surgical Innovations Limited
Ms. Shazia Chaudhry
Quality Assurance and Regulatory Manager
Clayton Wood House
6 Clayton Wood Bank
Leeds, West Yorkshire, LS16 6QZ, United Kingdom

Re: K190592
Trade/Device Name: YelloPort Elite Port Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 28, 2019
Received: March 7, 2019

Dear Ms. Chaudhry:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 801and Part 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190592

Device Name
YelloPort Elite Port Access System

Indications for Use *(Describe)*

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

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Surgical Innovations Ltd.
Traditional 510(k)
For YelloPort Elite Port Access System
510(k) Summary – 510(k)190592

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Surgical Innovations Ltd.

Submitter's Address:

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Telephone: +44(0)113 230 7597

Establishment Registration Number:

9680952

Contact Person:

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Date Prepared:

24 April 2019

The information below summarises the Device Classification Information regarding the YelloPort Elite Port Access System:

Primary Product Code:

Regulation Number	Device	Device Class	Product Code	Classification Panel
876.1500	Laparoscope, General & Plastic Surgery	Class 2	GCJ	General & Plastic Surgery

Device Trade Name:

YelloPort Elite Port Access System

Device Common Name:

YelloPort Elite Port Access System

Intended/ Indications Use:

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

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

Summary of Substantial Equivalence:

The predicate devices which are used to claim equivalence of the YelloPort Elite Port Access System are detailed in the summary table below.

Surgical Innovations Ltd.
Traditional 510(k)
For YelloPort Elite Port Access System
510(k) Summary – 510(k)190592

Summary of Comparison between Proposed Device and Predicate Device

General Information				
Property	***Proposed Device*** **YelloPort Elite Port Access System**	***Primary Predicate*** **YelloPort Plus Port Access System**	***Secondary Predicate*** **YelloPort Port Access System**	***Secondary Predicate*** **ENDOPATH XCEL Bladeless Trocar Universal Seal**
Common Name	**Laparoscope, General & Plastic Surgery**	**Laparoscope, General & Plastic Surgery**	**Laparoscope, General & Plastic Surgery**	**Laparoscope, General & Plastic Surgery**
Device Manufacturer	**Surgical Innovations**	**Surgical Innovations**	**Surgical Innovations**	**Ethicon Endo-Surgery, LLC**
Device Classification	**II**	**II**	**II**	**II**
Primary Product Code	**GCJ**	**GCJ**	**GCJ**	**GCJ**
510(k) Number	**N/A**	**K070712**	**K070712**	**K032676**
Environment	**Hospital**	**Hospital**	**Hospital**	**Hospital**
Intended Use/ Indication for Use	The YelloPort Elite Port Access System is indicated for use in laparoscopic procedures to give access to the abdominal cavity while maintaining pneumoperitoneum. The YelloPort Elite Port access system is also indicated for use in thoracoscopic procedures to give access to the thoracic cavity.	The YelloPort Plus Port Access System is indicated for use in laparoscopic procedures to give access to the abdominal cavity whilst maintaining pneumoperitoneum. The YelloPort Plus Port Access System is also indicated for use in laparoscopic procedures to give access to the thoracic cavity.	The YelloPort Port Access System is indicated for use in laparoscopic procedures to give access to the abdominal cavity whilst maintaining the pneumoperitoneum. The YelloPort Port Access System is also indicated for use in laparoscopic procedures to give access to the thoracic cavity.	The ENDOPATH XCEL Bladeless Trocar is intended for use in abdominal, thoracic and gynaecologic minimally invasive surgical procedures, to establish a path of entry for endoscopic instruments.
Trocar Types	Blunt Pencil point, Pyramidal Shielded (locking)	Blunt Pencil Point, Pyramidal Quill Shielded (locking and non-locking).	Blunt Pencil Point, Pyramidal Shielded (locking and non-locking).	N/A
Trocar / Cannula Diameter and Lengths	Available in 10 and 12 mm diameter; and in 75, 105 and 150 mm working lengths.	Available in 3, 5, 10, 12 and 16 mm diameter; and in 55, 70, 75, 95, 105 and 150 mm working lengths.	Available in 3.5, 5.5, 7.5, 10.5 and 12.5mm diameter; and in 55, 70, 95, 105 and 150 mm working lengths.	N/A
Comparison of Use:	Allows instruments from 5mm -12mm in diameter to be used.	Within the range, allows instruments from 5-12mm diameter to be used. .	Within the range, allows instruments from 5-12mm diameter to be used.	Allows instruments from 5mm-12mm in diameter to be used.
Trocar Patient Contacting Material	Stainless Steel	Stainless Steel	Stainless Steel	N/A
Trocar Supplied:	Non-sterile (Reusable)	Non-sterile (Reusable)	Non-sterile (Reusable)	N/A
Cannula Patient Contacting Materials	PEEK plastic	PEEK plastic	PEEK plastic	N/A

Cannula Supplied:	Non-sterile (Reusable)	Non-sterile (Reusable)	Non- sterile (Reusable)	N/A
Seal	Consists of : Non-Return Valve & Instrument Seal	Consists of : Non-Return Valve & Instrument Seal	Consists of : Non-Return Valve & Instrument Seal	Consists of : Non-Return Valve & Instrument Seal
Seal Supplied:	Sterile	Sterile	Sterile	Sterile
Hasson (Fascia) Adaptor	Available in both 10mm and 12mm diameter versions.	Available in both 10mm and 12mm diameter versions.	Available in both 10mm and 12mm diameter versions.	N/A
Hasson (Fascia) Adaptor	Fully reusable can be sterilised in pressurised steam.	Fully reusable can be sterilised in pressurised steam.	Fully reusable can be sterilised in pressurised steam.	N/A
Hasson (Fascia Adaptor) Contacting Materials	PEEK plastic	PEEK plastic	PEEK plastic	N/A

Any technical differences have been justified, both scientifically and using performance testing. These do not affect the safety or effectiveness of the proposed device.

Device Description:

The YelloPort Elite Port Access System comprises a trocar, available with a range of tip styles, cannula, Universal Seal and Hasson (fascia) adaptor. The trocar, cannula and Hasson (fascia) adaptor elements of the device are fully reusable and can be sterilised in pressurised steam. The Universal seal is single use only.

In order to obtain access to the surgical site during laparoscopic surgery, the YelloPort Elite Trocar is introduced into the YelloPort Elite Cannula to accomplish cannula penetration of the abdominal wall. The cannula is connected to the YelloPort Elite Universal Seal at its proximal end and once the abdominal/thoracic wall is punctured, the trocar is removed. The cannula acts as a channel for the introduction of the endoscopes and instruments. Generically, trocars and cannulas are available in a range of lengths and diameters.

Technological Characteristics:

A comparative review of the YelloPort Elite Port Access System with the predicate devices found that the technology, mode of operation, and general principles for treatment with this device were substantially equivalent to the predicate devices.

Non-Clinical Tests (Performance/Physical Data):

The YelloPort Elite Port Access System was evaluated for its safety and effectiveness based on the following testing:

- Sealing Performance
- Instrument Insertion Force (Universal Seal)
- Seal Contamination Testing
- Instrument Compatibility Testing (Universal Seal)
- Port Insertion Force Testing
- Insufflation Testing
- Seal Inversion Testing
- Trocar Knob Pull Testing
- Stopcock Torque Lever Test
- Universal Seal Attachment and Removal Test
- Cannula Mechanical Testing
- Pressure Retention of Universal Seal (With Use of Locking Shielded Trocar)
- Trocar Peritoneum Insertion Simulation Test (Locking Shielded)
- Torque Force Test (Locking Shielded)
- Tensile Test (Locking Shielded)
- Biocompatibility Testing in accordance with ISO 10993-1
- Shelf life and lifecycle studies
- Transit studies
- Cleaning and sterilisation validation
- Clinical (Design) validations which include a simulated surgical evaluation by a consultant surgeon
- Usability assessments.

Clinical Studies

No clinical studies were conducted as part of submission to prove substantial equivalence. Non-Clinical Bench testing was sufficient to prove equivalence to the predicate device.

Safety and Effectiveness/Conclusion:

Based on the information presented in these 510(k) premarket notifications the YelloPort Elite Port Access System is considered substantially equivalent. The YelloPort Elite Port Access System is as safe and effective as the currently marketed predicate devices.

Based on testing and comparison with the predicate device, the YelloPort Elite Port Access System shows no adverse indications or results. It is our determination that the YelloPort Elite Port Access System is safe, effective and performs within its design specifications and is substantially equivalent to the predicate devices.