June 18, 2021

Surgical Innovations Limited
Stephen Seed
Compliance Director
Clayton Wood House, 6 Clayton Wood Bank
Leeds, West Yorkshire LS16 6QZ
United Kingdom

Re: K210495
Trade/Device Name: Port Access System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 27, 2021
Received: June 1, 2021

Dear Stephen Seed:

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 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen, Ph.D.
Assistant Director
Non-Light Based Energy Devices Team
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K210495

Device Name
Port Access System

Indications for Use *(Describe)*
The Port Access System is indicated for use in laparoscopic procedures to give access to the abdominal and thoracic cavities while maintaining pneumoperitoneum.

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.

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Port Access System
Section 5: 510(k) Summary

I. Submitter

Surgical Innovations Limited
Clayton Wood House
6 Clayton Wood Bank
Leeds
LS16 6QZ
United Kingdom

Phone: +44 (0) 113 230 7597

Contact Person: Stephen Seed
Date Prepared: 25 March 2021

II. Device

Name of Device: Port Access System
Common Name: Laparoscopic Port System
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: GCJ

III. Predicate Device

YelloPort Elite Port Access System – K190592

The predicate has not been subject to any design-related recalls.

IV. Device Description

The Port Access System consists of reusable and single use components sold in various configurations. The ports accommodate laparoscopic instrument diameters from 5mm up to the diameter indicated on the chosen accompanying cannula. All single use parts are sterilised using gamma irradiation and supplied to the customer in a sterile condition.

In order to obtain access to the surgical site during laparoscopic surgery, the trocar is introduced into the cannula to accomplish cannula penetration of the abdominal wall. The cannula is connected to the single use 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.

V. Indications for Use

The Port Access System is indicated for use in laparoscopic procedures to give access to the abdominal and thoracic cavities while maintaining pneumoperitoneum.

VI. Comparison of Technological Characteristics with the Predicate Device

Property	*Proposed Device* Port Access System	*Primary Predicate* YelloPort Elite Port Access System
Common Name	**Laparoscope, General & Plastic Surgery**	**Laparoscope, General & Plastic Surgery**
Device Manufacturer	**Surgical Innovations**	**Surgical Innovations**
Device Classification	**II**	**II**
Primary Product Code	**GCJ**	**GCJ**
510(k) Number	**N/A**	**K190592**
Environment	**Hospital**	**Hospital**
Intended Use/ Indication for Use	The Port Access System is indicated for use in laparoscopic procedures to give access to the abdominal and thoracic cavities while maintaining pneumoperitoneum.	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.
Trocar Tip Geometries	Bladeless, Pencil point, Locking Shielded, Quill	Blunt, Pencil point, Pyramidal, Shielded (locking)
Trocar / Cannula Diameter and Lengths	Available in 5, 10 and 12 mm diameters; and in 55, 70, 95, and 105 and 150 mm working lengths.	Available in 10 and 12 mm diameter; and in 75, 105 and 150 mm working lengths.
Comparison of Use:	Allows instruments from 5mm -12mm in diameter to be used.	Allows instruments from 5mm -12mm in diameter to be used.
Trocar Patient Contacting Material	Single Use: Copolyester Reusable: Stainless Steel	Stainless Steel
Trocar Supplied:	Single Use: Sterile Reusable: Non-Sterile	Non-sterile (Reusable)
Cannula Patient Contacting Materials	Single Use: Copolyester Reusable: PEEK plastic	PEEK plastic
Cannula Supplied:	Single Use: Sterile Reusable: Non-Sterile	Non-sterile (Reusable)
Seal	Consists of: Non-Return Valve & Instrument Seal	Consists of: Non-Return Valve & Instrument Seal
Seal Supplied:	Sterile	Sterile

VII. Performance Data

A comparative review of the Port Access System with the predicate devices was conducted and the following performance data are provided in support of determining substantial equivalence of Port Access System to the predicate devices.

Biocompatibility

Biological evaluation of the single use and reusable components of the Port Access System was conducted in accordance with International Standard ISO 10993-1:2018 *Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process* and the US FDA guidance document *Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'* (2016 & 2020).

Non-Clinical Testing

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

- Sealing Performance
- Instrument Insertion Force (Universal Seal)
- Instrument Shaft Friction (Universal Seal)
- Instrument Compatibility (Universal Seal)
- Seal Contamination
- Insertion Force
- Insufflation
- Seal Core Inversion Testing
- Tensile
- Torque
- Endoscope Insertion/Retraction
- Fatigue
- Shelf Life
- Transit studies
- Cleaning & Sterilisation Validation
- Usability

Clinical Studies

No Clinical Studies were conducted as part of this submission. Non-Clinical Testing was sufficient to demonstrate substantial equivalence to the predicate device.

VIII. Conclusions

The information presented in the 510(k) premarket notifications demonstrates that the Port Access System is considered substantially equivalent to the predicate device. The Non-Clinical Bench Testing performed demonstrates that the Port Access System is safe, effective and performs within its design specifications and is substantially equivalent to the predicate devices. The Port Access System is as safe and effective as the currently marketed predicate devices.