AFS Medical Co. Ltd.
% Michele Lucey
Regulatory Affairs Advisor
Lakeshore Medical Device Consulting LLC
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K202688
Trade/Device Name: AFS Medical Sterile Single-Use Access Port System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OTJ, GCJ
Dated: September 3, 2021
Received: September 13, 2021

Dear Michele Lucey:

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,

Mark Trumbore
Acting Assistant Director
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

SECTION 5

FDA FORM 3881 INDICATIONS FOR USE

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)*

Device Name
AFS Medical Sterile Single-Use Access Port System

Indications for Use *(Describe)*

The AFS MEDICAL's Sterile Single-Use Access Port System for surgery is a manual device designed to access the peritoneal cavity during laparoscopic surgery minimally invasive surgery. Examples of procedures where the device may be used include colorectal, urological, and general surgery to access the surgical site

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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K202688
510(K) SUMMARY
As required by 21 CFR 807.92

Submitter Information:

Submitter's Name:	AFS Medical Co. Ltd.
Address:	Na-131, Ezen Mecha Zone, 117 Hwanggeum-ro Gimpo-Si Gyeonggi-do 10048, Republic of Korea
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Contact Person:	Michele Lucey
Telephone:	603-748-1374

Date Prepared: October 7, 2021

Device Trade Name: AFS Medical Sterile Single-Use Access Port System

Classification: 2

Classification Name: Single Incision Access System

Common or Usual Name: **Single Incision Access System**

Product Code(s): OTJ
Subsequent Product Code GCJ

Regulation Number(s): 878.1500

Primary Predicate Devices: GelPort Single Incision Access System (K090275),

Secondary Predicate: GelPort Laparoscopic Hand Access Device (K014047)
Reference Device: SILS™ Port, Model SILSPTT112A, K103253
Reference Device: OBP ONETRAC LX Illuminated Retractor
Reference Device GelPoint Advanced Access Platform (K110792)

Intended Use:

The AFS MEDICAL's Sterile Single-Use Access Port System for surgery is a manual device designed to access the peritoneal cavity during laparoscopic surgery. Examples of procedures where the device may be used include colorectal, urological, and general surgery to access the surgical site.

Device Description

The AFS MEDICAL's Sterile Single-Use Access Port System for surgery is a manual device designed to access the peritoneal cavity during laparoscopic surgery. The modular system can be used in a number of configurations as desired by the user. The system is named, JACK . System options include integrated LED lighting to provide additional intrabdominal illumination if desired, insufflation ports, and multiple cap/port options. Other device variants include retractor diameter, height, number of ports and port size configurations, number of LEDs, power line length, with disposable or external/rechargeable battery (to power light source). The device includes a receiving ring that allows for 360° rotation of the port during use.. The device includes blue light indicators on the port head to inform the user that the port head is correctly attached and sealed. The system includes Smart Tubing that contains LED lighting for additional illumination and holes connected to tubing for introduction of CO2 and removal of surgical smoke

Summary of Non-Clinical Testing:

The following performance tests were conducted. Testing focused on functional performance requirements consistent with the intended use of the device. Comparative testing to a reference device was conducted where appropriate.

Non-Clinical Performance Test Summary			
Study Name	Description	Reference Standard	Results
Leak, Instrument Insertion/Withdrawal, and Insufflation	Tests for leakage during instrument manipulation, measures insertion an withdrawal forces, results must be equivalent when compared to the reference device. Test also confirms insufflation port performance at 20 LPM.	NA	Insertion, withdrawal, leak, and insufflation performance were acceptable, Pass
Smoke evacuation	Assessed smoke evacuation performance under simulated use conditions	NA	Smoke evacuation performance was acceptable, Pass
Power line connection force	Tests the security of power line connection to the controller unit. Force to disconnect must be >30N	NA	Power line connection force was > 30 N, Pass
LED Intensity and Holding Time	Intensity is measured by an illuminometer in a dark room and must be >30 000 lux illumination must maintain a holding time for at least one hour	NA	Illumination and holding time met the acceptance criteria, Pass
Electrical Safety Testing	Must meet relevant clauses	IEC 60601-1	All requirements were met, Pass
Electromagnetic Compatibility	Must meet relevant clauses	IEC 60601-1-2	All requirements were met, Pass

Biocompatibility Testing Summary

Categorized as Externally Communicating Device, Limited Contact (≤ 24 hours), per ISO 10993-1, the following testing was conducted:

Test Name	Test Method	Results
Cytotoxicity	Tested in accordance with ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* toxicity, Neutral Red Uptake Method	Pass Noncytotoxic according to the predetermined acceptance criteria
Intracutaneous Irritation	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Pass Test requirements for intracutaneous reactivity were met according to the predetermined acceptance criteria
Sensitization	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitization, Kligman Maximization Test	Pass did not elicit a sensitization response according to the predetermined acceptance criteria

Clinical Testing

Real-world data was collected from two independent clinical sites in Austria. Results from procedures performed by multiple clinicians reported no adverse events related to the device and assessed performance of all key attributes as acceptable.

Predicate Device Comparison

The following table provides a comparison of the key characteristics of the AFS Medical Sterile Single-Use Access Port System to the predicate devices.

Comparison chart				
Feature	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Comparison**
	AFS Medical Sterile Single-Use Access Port System	Applied Medical GelPort Single Incision Access System	Applied Medical GelPort Single Incision Access System	
Regulatory Clearance/ Approval Reference	Pending	K090275	K014047	NA
FDA Classification	Class II	Class II	Class II	Class II
Product Code(s)	OTJ	GCJ	OTJ	GCJ
Regulation Number	876.1500	876.1500	876.1500	876.1500
Anatomical Location	Abdomen	Abdomen	Abdomen	Abdomen
Insertion	Through an incision	Through an incision	Through an incision	Through an incision

Comparison chart				
Feature	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Comparison**
	AFS Medical Sterile Single-Use Access Port System	Applied Medical GelPort Single Incision Access System	Applied Medical GelPort Single Incision Access System	
Anchoring	Secured to the patient vis a sleeve type wound protector	Secured to the patient vis a sleeve type wound protector	Secured to the patient vis a sleeve type wound protector	Secured to the patient vis a sleeve type wound protector
Mechanism of Action	Serves as a wound retractor and access port for surgical instruments	Serves as a wound retractor and access port for surgical instruments	Serves as a wound retractor and access port for surgical instruments	Serves as a wound retractor and access port for surgical instruments
Retractor diameter	45-130mm	Multiple diameters (40-120mm)	Multiple diameters (40-120mm)	Similar, difference in the overall design and principal of operation are minor and do not raise questions of safety or efficacy as the general principle for use is the same
Access Mechanism	Integrated ports of various sizes and number	Trocars are inserted directly through the gel cap to create a port to introduce instruments	Trocars are inserted directly through the gel cap to create a port to introduce instruments	Similar, difference in the overall design and principal of operation are minor, access is achieved in the same manner and do not raise questions of safety or efficacy as the general principle for use is the same.
Port sizes	5-15mm	NA, trocars are placed through gel cap	NA, trocars are placed through gel cap	Difference does not affect the mechanism of action, access is achieved in a similar fashion and does not raise questions of safety or efficacy.

Comparison chart				
Feature	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Comparison**
	AFS Medical Sterile Single-Use Access Port System	Applied Medical GelPort Single Incision Access System	Applied Medical GelPort Single Incision Access System	
Port Number	1-4	NA, trocars are placed through gel cap	NA, trocars are placed through gel cap	Difference does not affect the mechanism of action, access is achieved in a similar fashion and do not raise questions of safety or efficacy.
Requires Trocar	No, includes ports for instrument insertion	Yes	Yes	Difference does not affect the mechanism of action, access is achieved in a similar fashion, however the AFS devices eliminate the need for a sharp trocar blade to be inserted. Difference does not raise questions of safety or efficacy.
Incision size	1.6-9 cm	1.5-9 cm	1.5-9 cm	Same
Incision retraction angle	360°	360°	360°	Same
Hand Access	Yes, by cap removal	Yes, by cap removal	Yes, by insertion through the slit in the Gel Cap	Same
Insufflation/smoke evacuation ports	Yes, two ports	No	No	Performance comparison to reference device confirmed equivalent performance. This difference does not raise questions of safety or efficacy
Battery powered integrated illumination	Yes, on some models	No	No	Illumination is adjunct and is not a replacement for

Comparison chart				
Feature	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Comparison**
	AFS Medical Sterile Single-Use Access Port System	Applied Medical GelPort Single Incision Access System	Applied Medical GelPort Single Incision Access System	
				standard illumination (endoscope), difference does not affect the mechanism of action of the device. This feature is found in other surgical device accessories (illuminated retractors with LED light Source and Smoke Evacuation, battery operated (Class I), OBP ONETRAC LX). Difference does not raise questions of safety or efficacy.
Materials – Sterile Single Use System Components	Various polymers and stainless steel	Various polymers, stainless steel, and lubricant	Various polymers, stainless steel, and lubricant	Same
Instrument Capability	Endoscopic instruments ranging in size from 5-25mm	Endoscopic instrument size not specified	Endoscopic instrument size not specified	Same, though predicate is nonspecific
Instrument Articulation	Yes, by means of flexible ports	Yes, by means of a flexible membrane	Yes, by means of a flexible membrane	Same
Cap to sealing ring seal indicator	Blue lights when lit indicate the cap is sealed to the sealing ring	No	No	Difference does not affect the mechanism of action of the device and does not raise questions of safety or efficacy
Sealing ring rotation	360°	Fixed	Fixed	Difference does not affect the mechanism

Comparison chart				
Feature	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Comparison**
	AFS Medical Sterile Single-Use Access Port System	Applied Medical GelPort Single Incision Access System	Applied Medical GelPort Single Incision Access System	
				of action of the device and does not raise questions of safety or efficacy.
Insufflation ports	Yes	No	No	Insufflation for the GelPort is through the cap via the trocar. Difference does not affect the mechanism of action of the device and does not raise questions of safety or efficacy.
Maintains insufflation while articulating instruments	Yes	Yes	Yes	Same
Convert to open procedure	Yes, by removal of the Port Head, retractor remains	Yes, by removal of the Gel Cap, retractor remains	Yes, by removal of the Gel Cap, retractor remains	Same
How Supplied	Sterile, single use	Sterile, single use	Sterile, single use	Same
Sterilization Method	EtO	Unknown	Unknown	This difference does not affect the sterilization status of the device
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	Same

Conclusion:

Based on a review of bench top assessments, comparison of the device classification, intended use, operating principle, technological characteristics, sterility, and biocompatibility the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.