April 8, 2026

Suzhou Shenyun Medical Equipment Co., Ltd.
℅ Rachel Yu
Regulatory Affair Manager
Zhihe Info-Tech(Suzhou) Co., Ltd.
Bldg. 1, # 1 Huayun Rd., Industrial Park
Suzhou, Jiangsu 215000
China

Re: K260197
Trade/Device Name: Shogun Axis™ Fascial Closure System (1018S, 1018B, 1218S, 1218B, 1518S, 1518B)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 16, 2026
Received: January 22, 2026

Dear Rachel Yu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.04.08 19:17:55 -04'00'

James Jang, Ph.D.
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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260197

Please provide the device trade name(s).

Shogun Axis™ Fascial Closure System (1018S, 1018B, 1218S, 1218B, 1518S, 1518B)

Please provide your Indications for Use below.

The Shogun Axis™ Fascial Closure Systems (Optical & Bladeless) are intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K260197

510(k) Summary

Prepared on: 2026-04-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Suzhou Shenyun Medical Equipment Co., Ltd.
Applicant Address	Building 11, No. 666, Yinzang Road, Linhu Town, Wuzhong District, Suzhou Jiangsu 215105 China
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Correspondent Contact Telephone	+86 13761082592
Correspondent Contact	Ms. Rachel Yu
Correspondent Contact Email	rachel.yu@zhihese.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Shogun Axis™ Fascial Closure System (1018S, 1018B, 1218S, 1218B, 1518S, 1518B)
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K163654	VersaOne Fascial Closure System Bladed Trocar, VersaOne Fascial Closure System Bladeless Trocar, VersaOne Fascial Closure System Optical Trocar	GCJ
K980123	Carter-Thomason II Port Closure System (legacy clearance holder : CARTER-THOMASON NEEDLE-POINT SUTURE PASSER INSTRUMENT SET)	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The Shogun Axis™ Fascial Closure Systems (Optical & Bladeless) are intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

The Shogun Axis Fascial Closure System is a sterile, single-use laparoscopic access and port-site closure system. The system consists of a cannula assembly with an integrated valve and insufflation port, an obturator used to establish abdominal access, and an integrated fascial closure feature that enables placement of sutures to facilitate closure of port-site defects following laparoscopic procedures.
The device is provided in two obturator configurations (optical obturator and bladeless obturator) and three nominal cannula sizes (10 mm, 12 mm, and 15 mm), with a nominal cannula working length of 110 mm. The cannula includes a stopcock and a standard luer connection for insufflation, and incorporates internal seals intended to maintain pneumoperitoneum when instruments are inserted or exchanged.
The fascial closure feature comprises two opposed guide channels integrated into the cannula to direct a single-use suture passer for controlled suture placement. Suture is not provided with the device. The device is supplied ethylene oxide sterilised and is intended for single-use only.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Shogun Axis™ Fascial Closure Systems (Optical & Bladeless) are intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Shogun Axis™ Fascial Closure System has the same indications for use as the primary predicate device, VersaOne™ Fascial Closure System (K163654). Both subject device and predicate device are intended for use in a variety of minimally invasive gynecologic, general, and urologic procedures to create and maintain a port of entry for laparoscopic instruments. The indications for use of the subject device and the predicate device are only different in expression which will not exert influence on safety and effectiveness of the product.

Technological Comparison 21 CFR 807.92(a)(6)

The Shogun Axis™ Fascial Closure System (subject device), the VersaOne Fascial Closure System (primary predicate device, K163654), and the Carter-Thomason II Port Closure System (secondary predicate device, K980123) share similar technological characteristics, as outlined below:

1.Principles of operation (trocar insertion, obturator removal, cannula maintenance of pneumoperitoneum, and suture passage through distal channels for fascial closure).
2.Configurations (Optical and Bladeless), which share the same stainless steel (SUS304) obturator shaft and polycarbonate distal tip; the distal tip colour differs (transparent for optical, black for bladeless).
3.Core structures (transparent cannula, obturator).
4.Patient-contacting materials and biocompatibility compliance (ISO 10993 series).
5.Sterilization (EO) and single-use status (with predicate using reusable suture passer separately).
The primary difference is the integration of a single-use suture passer within the Shogun Axis™ sterile pack, whereas the primary predicate device utilizes a separately provided reusable suture passer. Mechanical performance of the suture passer was evaluated through comparison with the secondary predicate device, Carter-Thomason II Port Closure System (K980123).

Dimensional variations fall within clinically accepted ranges. System-level performance, including access, sealing, fixation, and visualization, is comparable to that of the primary predicate device.

These differences do not raise new questions of safety or effectiveness and were verified through bench testing. All differences in technological characteristics have been addressed through bench testing, engineering analysis, and usability evaluation, demonstrating that the subject device is as safe and effective as the identified predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following non-clinical testings were performed to support the safety and performance of the Shogun Axis Fascial Closure System. The test results demonstrated that the subject device complies with the standard requirements.

(1) Bench performance tests

Bench performance testing was conducted under reports Performance Test Report and Performance Comparison Testing Report, with testing items including:

Trocar-cannula assembly

- Visual examination
- Dimensional verification
- Functional performance
- Flexibility (valve and cap function)
- Connection security
- Luer lock performance (ISO 80369-7, clause 6.5, 6.6)
- Cannula and seal leakage integrity
- Tissue interface leakage integrity
- Cannula fixation force
- Corrosion resistance
- Trocar penetration force
- Trocar insertion force and extraction force
- Trocar insertion force into cannula
- Optical visualization evaluation (optical configuration only)

Suture passer assembly
- Visual examination
- Dimensional verification
- Functional performance
- Connection security
- Corrosion resistance
- pH test
- Rigidity
- Toughness
- Needle penetration force
- Actuation force (handle opening force)
- Suture retention force

(2) Packaging integrity and shelf-life testing
Shelf-life for the Shogun Axis Fascial Closure System was established as 3 years based on accelerated aging per ASTM F1980-21. Package integrity was validated per ISO 11607-1/-2 using representative paper-plastic bag configurations, with testing (visual inspection, seal strength, dye penetration, bubble leak, and bacterial barrier challenge) performed pre- and post-accelerated aging.

(3) Human Factors evaluations were completed using:
Human factors/usability engineering evaluations (formative and summative) were conducted in accordance with IEC 62366-1 and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" (February 3, 2016). Summative testing with 15 representative users in simulated conditions confirmed safe and effective use of critical tasks with no serious use errors. Results demonstrate acceptable residual use-related risk.

The clinical data is not applicable. No clinical performance report(s) is being submitted.