October 30, 2026

Strauss Surgical USA
% Rob Packard
Senior Regulatory Consultant
Medical Device Academy
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05788

Re: K263075
Trade/Device Name: Strauss Surgical Cystoscope/Hysteroscope and Accessories Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: September 1, 2026
Received: September 2, 2026

Dear Rob Packard:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See

the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.	K263075

Please provide the device trade name(s).

Strauss Surgical Cystoscope/Hysteroscope and Accessories Instruments

Please provide your Indications for Use below.

Endoscopes:
Cystoscopes/Hysteroscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples for the use of the devices include the visualization and manipulation of the anatomy, as the surgeon deems appropriate. The Cystoscopes/Hysteroscopes are intended to be used in general urological and gynecological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.

Urology Instruments:
The Urology Instruments in combination with endoscopes are intended to provide the user with the means for endoscopic visualization during examination, diagnosis and therapy of the lower urinary tract in conjunction with endoscopic accessories, or as the surgeon deems appropriate. The instruments are intended for use in urological procedures through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) #:

510(k) Summary

Prepared on: 2026-09-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Strauss Surgical USA
Applicant Address	3020 NW 82nd Ave Doral FL 33122 United States
Applicant Contact Telephone	+1.305.468.1455
Applicant Contact	Mr. Antonio Nava
Applicant Contact Email	antonio.nava@straussurgical.com
Correspondent Name	Medical Device Academy
Correspondent Address	345 Lincoln Hill Rd Shrewsbury VT 05788 United States
Correspondent Contact Telephone	+1.802.258.1881
Correspondent Contact	Mr. Rob Packard
Correspondent Contact Email	rob@fdaestar.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Strauss Surgical Cystoscope/Hysteroscope and Accessories Instruments
Common Name	Endoscope and accessories
Classification Name	Cystoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FAJ, HIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K260271	Cystoscope 4.0mm autoclavable 0° WL 302mm; Hysteroscope 4.0mm autoclavable 0° WL 302mm; Cysto-Urethroscope Sheath 19 Fr.; Bridge for 17-25 Fr. Cysto-Urethroscope Sheath	FAJ

Device Description Summary

21 CFR 807.92(a)(4)

Cystoscopes, Hysteroscopes and Accessories are composed of cystoscopes, hysteroscopes and cystoscopic accessories, which provide the user with the means for endoscopic diagnostic and therapeutic procedures. Examples of use of the product include the visualization and manipulation of anatomy, biopsy, and as the surgeon deems appropriate.

The subject device includes the following components:

• Cystoscope /Hysteroscopes: A rigid or flexible endoscopic instrument designed for direct visualization of the urethra and urinary bladder. It consists of an optical system (telescope), an illumination source, and working channels that allow the introduction of instruments for diagnostic and therapeutic procedures such as biopsies, stone removal, or stent placement.

• Sheaths – Outer tubular component that serves as the access conduit during cystoscopy. It provides irrigation and drainage channels to maintain clear visualization, and allows for the introduction of instruments into the bladder. The sheath connects with the bridge and obturator to form the working assembly.

• Obturators – A smooth-tipped guiding element inserted through the cystoscopic sheath to facilitate atraumatic insertion into the urethra. Once access is achieved, the obturator is removed, allowing the sheath to remain in place for the procedure.

• Visual Obturator – A specialized obturator with an optical channel that accommodates the telescope, enabling direct visualization during insertion. It ensures safe, controlled advancement of the sheath under continuous endoscopic view.

• Bridge – An intermediate component that connects the cystoscopic sheath to the telescope and accessory instruments. It provides ports for irrigation and instrument entry, enabling controlled manipulation during diagnostic and therapeutic procedures.

• Albarran deflectors: A built-in mechanical deflection mechanism located in the bridge or sheath assembly. It allows precise angulation and control of accessory instruments, such as guidewires or forceps, facilitating access to the ureteral orifices.

• Optical Forceps: Endoscopic grasping instruments equipped with an integrated optical channel for direct visualization during tissue manipulation or foreign body retrieval. They enable precise control and visualization through the telescope.

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

Endoscopes:
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Urology Instruments:
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Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject and predicate devices have the same intended use and the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

Below is the summary of comparison of the technological characteristics of the subject device. These technological characteristics of the subject device are same as the predicate device.

Working length (± 0.5mm)- 269mm – 302mm

Outer diameter (± 0.2mm)- 2.7mm – 4.0mm

Distal Tip (Outer Diameter)- 2.7mm – 4.0mm

Light Source- Xenon, LED

Deflection (°)- 0°- 70°

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

Below is the summary of non-clinical tests performed:

• Bench testing was conducted to verify the performance of the Cystoscopes, Hysteroscopes, and Accessories. Design verification testing was conducted to evaluate the mechanical, optical, and illumination performance.

• Below Biocompatibility testing was performed according to ISO 10993-1:

Cytotoxicity Test- ISO 1993-5

• The cleaning instructions were also validated. The Strauss Surgical Cystoscopes, Hysteroscopes, and Accessories has been validated for manual and automated cleaning as well as steam sterilization to provide a sterility assurance of 10-6.

•The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971.

The subject devices demonstrate conformance with the following recognized standards and guidances:

• 510(k) submission guidance for Hysteroscopes and Gynecology Laparoscopes;
• IEC 60601-2-18, Sec. 201.11.1.2.2
• ISO 8600-1;
• ISO 8600-3;
• ISO 8600-4;
• ISO 8600-5;
• ISO 8600-6.

Results of all non-clinical testing demonstrates that the subject device is as safe, as effective and performs same as the predicate device.