April 16, 2026

Strauss Surgical USA
% Shaily Shah
Regulatory Consultant
Medical Device Academy, Inc.
135 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K253892
Trade/Device Name: Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302ASA HD-endoscope, 4 x 302 mm, view. Dir. 0 , standard, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302AA HD-endoscope, 4 x 302 mm, view. Dir. 0 , wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BA HD-endoscope, 4 x 302 mm, view. Dir. 30 , wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BSA HD-endoscope, 4 x 302 mm, view. Dir. 30, standard, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302ESA HD-endoscope,4 x 302 mm, view. Dir. 12 , standard, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302CA HD-endoscope, 4 x 302mm, view. Dir. 70 , wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2029-302AA HD-endoscope, 2.9 x 302 mm, view. Dir. 0 , wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2029-302BA HD-endoscope, 2.9 x 302 mm, view.)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, HIH
Dated: December 4, 2025
Received: December 4, 2025

Dear Shaily Shah:

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.

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,

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.	K253892

Please provide the device trade name(s).

Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302ASA HD-endoscope, 4 x 302 mm, view. Dir. 0°, standard, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302AA HD-endoscope, 4 x 302 mm, view. Dir. 0°, wide angle, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BA HD-endoscope, 4 x 302 mm, view. Dir. 30°, wide angle, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BSA HD-endoscope, 4 x 302 mm, view. Dir. 30°, standard, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302ESA HD-endoscope,4 x 302 mm, view. Dir. 12°, standard, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302CA HD-endoscope, 4 x 302mm, view. Dir. 70°, wide angle, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2029-302AA HD-endoscope, 2.9 x 302 mm, view. Dir. 0°, wide angle, autoclavable);
Strauss Surgical Cystoscopes & Hysteroscopes (STS-2029-302BA HD-endoscope, 2.9 x 302 mm, view. Dir. 30°, wide angle, autoclavable)

Please provide your Indications for Use below.

Strauss Surgical Cystoscopes are intended to illuminate and visualize the male urethra, prostate, and bladder for the purpose of performing diagnostic and surgical procedures.

Strauss Surgical Hysteroscopes are intended to illuminate and visualize the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

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) #: K253892

510(k) Summary

Prepared on: 2026-03-24

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	+1.305.4681455
Applicant Contact	Mr. Antonio Nava
Applicant Contact Email	antonio.nava@strausssurgical.com
Correspondent Name	Medical Device Academy, Inc.
Correspondent Address	135 Lincoln Hill Rd Shrewsbury VT United States
Correspondent Contact Telephone	617.774.7542
Correspondent Contact	Mrs. Shaily Shah
Correspondent Contact Email	shaily@fdaestar.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302ASA HD-endoscope, 4 x 302 mm, view. Dir. 0°, standard, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302AA HD-endoscope, 4 x 302 mm, view. Dir. 0°, wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BA HD-endoscope, 4 x 302 mm, view. Dir. 30°, wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BSA HD-endoscope, 4 x 302 mm, view. Dir. 30°, standard, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302ESA HD-endoscope,4 x 302 mm, view. Dir. 12°, standard, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302CA HD-endoscope, 4 x 302mm, view. Dir. 70°, wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2029-302AA HD-endoscope, 2.9 x 302 mm, view. Dir. 0°, wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2029-302BA HD-endoscope, 2.9 x 302 mm, view. Dir. 30°, wide angle, autoclavable)
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
K251652	Strauss Surgical Cystoscopes & Hysteroscopes	FAJ

Device Description Summary 21 CFR 807.92(a)(4)

The cystoscopes/hysteroscopes described herein are rigid endoscopes for visualizing the urethra, the urinary bladder or uterus, ostium and the cervical canal during the performance of endoscopic procedures in urology or gynecology.

A rigid endoscope consists of a fiber optic cable and sensitive image transmission system with eyepiece.

The fiber optic cable is used to illuminate the site inside the body. The connector for connecting the light guide to the light source is situated at the proximal end of the endoscope. The adapters required to connect the light guide are included in the scope of delivery.

The distal end of the endoscope features an objective lens that captures the image from inside the body. The image is sent through the image transmission system to the eyepiece.

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

Strauss Surgical Cystoscopes are intended to illuminate and visualize the male urethra, prostate, and bladder for the purpose of performing diagnostic and surgical procedures.

Strauss Surgical Hysteroscopes are intended to illuminate and visualize the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

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

The subject device's indications for use is equivalent to indications for use as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices have identical technological characteristics. Below is the summary of the technological characteristics:

Light that is created by an external light source is transmitted from the endoscope's light guide connector through the endoscope itself to the tip via a fiber optic system. Images are transferred the other way back through a rigid lens system.

Technical parameters of the Strauss Cystoscopes/Hysteroscopes that characterize the optical view are the Direction of View (0°-70°) and the Field of View (63°-85°).

The image can be displayed by a camera/monitor system which can be connected to the endoscope eyepiece.

Models of the Strauss Cystoscopes/Hysteroscopes have the same diameter and length of the insertion tube that is (2.9mm; 4mm/ 302mm).

Similar to the predicate device, none of the endoscope models have a working channel.

Like other currently marketed rigid cystoscopes and hysteroscopes, all endoscope models have outer surfaces mainly made from metal (Phynox cobalt-nickel-chromium stainless steel alloy, 304 stainless steel) and incorporate fiber optics for light transmission and rigid lenses for image transmission.

The subject device requires same reprocessing methods as used for the predicate device. The reprocessing methods includes cleaning(manual and automated), high level disinfection and sterilization (steam).

The subject device same manufacturer, same manufacturing facility, same materials, material grades, same component suppliers, same manufacturing process and same tissue contact type and duration as the predicate device.

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

The subject and predicate devices have identical technological characteristics. Therefore, no performance testing was necessary to

demonstrate that the subject device is equivalent to the predicate device in terms of safety and performance.