September 23, 2025

Zenflow, Inc.
Marianne Jacklyn
Regulatory Affairs Director (contractor)
395 Oyster Point Blvd.
Suite 501
South San Francisco, California 94080

Re: K251140
Trade/Device Name: Zenflow Spring Scope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: August 25, 2025
Received: August 26, 2025

Dear Marianne Jacklyn:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 J. ANTONINO -S

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.	K251140

Please provide the device trade name(s).

Zenflow Spring Scope

Please provide your Indications for Use below.

The Zenflow Spring Scope is a sterile, single use flexible cystoscope intended to provide endoscopic access and visualization of the lower urinary tract. The Zenflow Spring Scope is intended for use with the separately provided Zenflow Camera Control Unit and which provides visualization via any commercially available compatible video monitor. The Zenflow Spring Scope can be used with compatible endoscopic accessories.

The Zenflow Spring Scope is intended for use in a hospital environment or medical office environment.

The Zenflow Spring Scope is designed for use in adults.

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

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

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1 Contact Details: 21 CFR 807.92(a)(1)

Applicant Name	Zenflow, Inc.
Applicant Address	395 Oyster Point Blvd. Suite 501 South San Francisco, CA 94080 USA
Applicant Contact Telephone	Phone: 503-729-9633
Applicant Contact	Ms. Marianne Jacklyn
Applicant Contact Email	mjacklyn@zenflow.com

2 Device Name: 21 CFR 807.92(a)(2)

Trade Name	Spring Scope
Common Name	Endoscope and accessories
Classification Name	Cystoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FAJ

3 Legally Marketed Predicate Devices: 21 CFR 807.92(a)(3)

K193095, Ambu aScope 4 Cysto

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

The Zenflow Spring Scope is a sterile, single-use flexible cystoscope which is compatible only with the separately provided Zenflow Camera Control Unit (CCU), which provides direct visualization of the lower urinary tract via any commercially compatible video monitor. The Zenflow Spring Scope (Spring Scope) incorporates markings on the shaft along with a slider that may be used to reference anatomical positions. The Spring Scope has a lever that enables anterior steering, and a built-in steering lock which holds the Spring Scope in a deflected (anterior) position. The working channel provides access for compatible endoscopic devices and instrumentation. The Spring Scope is for single patient use only.

The Spring Scope houses a CMOS-based imaging sensor and LED for anatomic visualization. Cystoscopic digital imaging allows for direct visualization of the bladder and urethra. The Spring Scope handle also contains a luer port which is used to connect with an irrigation line.

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

The Zenflow Spring Scope is a sterile, single use flexible cystoscope intended to provide endoscopic access and visualization of the lower urinary tract. The Zenflow Spring Scope is intended for use with the separately provided Zenflow Camera Control Unit and which provides visualization via any commercially compatible video monitor. The Zenflow Spring Scope can be used with compatible endoscopic accessories.

The Zenflow Spring Scope is intended for use in a hospital environment or medical office environment.

The Zenflow Spring Scope is designed for use in adults.

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

The indications for use for the subject device are the same as the predicate device.

7 Technological Comparison: 21 CFR 807.92(a)(6)

Device & Predicate Device(s)	**Subject Device K251140**	**Predicate Device K193095**
Indications for Use	The Zenflow Spring Scope is a sterile, single-use flexible cystoscope intended to provide endoscopic access and visualization of the lower urinary tract. The Zenflow Spring Scope is intended to be used with the separately provided Zenflow Camera Control Unit, which enables visualization through any commercially available compatible video monitor. The Zenflow Spring Scope is compatible with various endoscopic accessories. The Zenflow Spring Scope is intended for use in a hospital environment or medical office environment. The Zenflow Spring Scope is designed for use in adults.	Ambu® aScope™ 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Ambu® aScope™ 4 Cysto is intended to provide visualization via Ambu® displaying unit and can be used with endoscopic accessories. Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment. Ambu® aScope™ 4 Cysto is designed for use in adults.
Reusability	Single use	Single Use
Energy Source	Electricity	Electricity

Device & Predicate Device(s)	**Subject Device K251140**	**Predicate Device K193095**
Digital Video Technology	CMOS	CMOS
Illumination Source	LED	LED
Field of View	90° ± 10° vertical/horizontal 120° ± 10° diagonal	120°± 10° diagonal
Direction of View	0°	0°
Depth of Field	3 to 100 mm	3 to 100 mm
Maximum Insertion Portion Width	20 Fr	18 Fr
Working Length	345 mm	390 mm
Working Channel Size	4.0 mm	2.2 mm
Deflection	Up: 180°	Up: 210° Down: 120°

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

A series of nonclinical tests, listed below, were performed to assess the safety and effectiveness of the Zenflow Spring Scope. All tests were conducted utilizing devices after sterilization and accelerated or real time aging.

- Bench testing:
  - Simulated use testing
  - Testing of image quality
  - Testing of compatibility with accessories
  - Testing of flush flow rate
  - Testing of tensile strength
  - Fatigue testing
  - Measurement accuracy
- Biocompatibility evaluation according to ISO 10993-1 Fifth edition 2018-08 and related FDA Guidance
- Sterilization validation according to ISO 11135 Second edition 2014-07-15 and ISO 10993-7 Second edition 2008-10-15

- Electrical Safety and EMC testing according to IEC 60601-1-2 Edition 4.1 2020-09, IEC 60601-2-18 Edition 3.0 2009-08, and IEC 62471 First edition 2006-07

9 Conclusions From Non-Clinical Tests: 21 CFR 807.92(b)

The conclusions drawn from the technological comparison and nonclinical testing demonstrate that the proposed subject devices raise no new questions of safety or effectiveness, and are substantially equivalent in terms of safety and effectiveness as the legally marketed predicate devices for the proposed indications for use.