May 11, 2026

Verathon Medical (Canada) Ulc
Curtis Jensen
Sr. Regulatory Affairs Specialist
2227 Douglas Rd.
Burnaby, BC V5C 5A9
CANADA

Re: K253696
Trade/Device Name: CFlex Cystoscope - Standard Deflection (0570-0455);
CFlex Cystoscope - Reverse Deflection (0570-0456);
CystoView Monitor (0570-0465)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, FET
Dated: April 15, 2026
Received: April 16, 2026

Dear Curtis Jensen:

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.	K253696

Please provide the device trade name(s).

CFlex Cystoscope - Standard Deflection (0570-0455);
CFlex Cystoscope - Reverse Deflection (0570-0456);
CystoView Monitor (0570-0465)

Please provide your Indications for Use below.

The CFlex Single-use Cystoscope is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The cystoscope is intended to provide visualization via compatible Verathon monitor and can be used with endoscopic accessories.

The cystoscope is intended for use in adults requiring cystoscopy by qualified urology professionals in a clinic, hospital or ambulatory surgery center (ASC) environment.

The CystoView monitor is intended to display live imaging data from the CFlex Single-use Cystoscope.

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)

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510(k) Summary

This summary of Safety and Effectiveness is provided as part of this Premarket Submission.

Submitter:	Verathon Medical (Canada) ULC 2227 Douglas Road Burnaby, BC V5C 5A9 Canada
Contact Person:	Curtis Jensen Sr. Regulatory Affairs Specialist Phone: (425) 629-5530 Email: curtis.jensen@verathon.com
Date Summary Prepared:	April 15, 2026
Trade Name:	CFlex Single-Use Cystoscope and CystoView Monitor
Common/Usual name:	Endoscope and Endoscope Video Imaging System/Component
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500, Class II Classification Product Code: FAJ, FET
Predicate Device:	Ambu aScope 5 Cysto HD (Standard and Reverse Deflection) and aView 2 Advance Gen. 2 Monitor 510(k) # K240848
Reference Device:	Ambu aScope 4 Cysto 510(k) # K193095
Review Panel:	Reproductive, Gynecology and Urology Devices

Device Description:
The CFlex Single-use Cystoscope is an endoscope with a flexible shaft which houses a cylindrical working channel, components to allow the distal end to be articulated, and a high-resolution camera at the distal tip.

The CystoView is a reusable single input monitor to be used for visualization when the CFlex is being used. The monitor contains proprietary Verathon operating software and a touchscreen display that serves as the user interface. The touchscreen display allows the user to display live and stored images/video, manage and transfer stored images/video to a USB drive, and customize settings. The monitor also incorporates an integrated cable holder to secure the compatible QuickConnect cable. The system also includes a rechargeable battery.

Intended Use/Indications for Use:

The CFlex Single-use Cystoscope is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The cystoscope is intended to provide visualization via compatible Verathon monitor and can be used with endoscopic accessories.

The cystoscope is intended for use in adults requiring cystoscopy by qualified urology professionals in a clinic, hospital or ambulatory surgery center (ASC) environment.

The CystoView monitor is intended to display live imaging data from the CFlex Single-use Cystoscope.

Technological Comparison:

The proposed subject CFlex Single-Use Cystoscope and CystoView Monitor when compared to the predicate Ambu aScope 5 Cysto HD and aView 2 Advance Gen. 2 Monitor has similar technological characteristics. See the comparison table below for similarities and differences between the proposed and predicate devices:

Technological Characteristic	Predicate Device Ambu aScope 5 Cysto HD and aView 2 Advance Gen. 2 Monitor (K240848)	Subject Device CFlex and CystoView (This submission)
Flexible Endoscope	Yes	Yes
Bending angle	210° ± 15° up 120° down	210° up 210° down
Shaft outside diameter	5.4 mm	5.0 mm (15 Fr.)
Maximum diameter of insertion portion	6.0 mm	5.7 mm (17.1 Fr.)
Working Length	388 mm	390 mm
Image sensor technology	CMOS (claimed “HD”)	CMOS (400x400px)
Direction of view	0°	Same
Field of view	120° Unknown	120° (diagonal) 85° (horizontal/vertical)
LED light source	Yes	Yes
Min. working channel inner diameter	2.2 mm (6.6 Fr.)	2.4 mm (7.2 Fr.)

Technological Characteristic	Predicate Device Ambu aScope 5 Cysto HD and aView 2 Advance Gen. 2 Monitor (K240848)	Subject Device CFlex and CystoView (This submission)
Method of sterilization for cystoscope	Ethylene Oxide (ETO)	Same
Single-Use Cystoscope	Yes	Yes
Control lever for tip maneuverability	Yes	Yes
Camera	Yes	Yes
Irrigation fluid flow control	Roller clamp or separately-purchased stopcock accessory	Integrated stopcock and fluid flow control lever
Image display	Displays image on a reusable monitor	Same
Image display size	12.8” (diagonal)	15.6 inch (diagonal)
Power source	Rechargeable Lithium-Ion battery	Same
IP Protection Classification – CystoView Monitor	IP31	IP54
Compatibility with Endoscopic accessories and instruments	Irrigation set, Syringe and other Luer connecting accessories, endoscopic instruments labeled for use in a working channel size of (ID) 2.0mm/6.0 Fr or less, Access sheath with an inner diameter of no less than 20 Fr., Holmium YAG laser, Thulium fiber laser, high frequency surgical equipment fulfilling EN 60601-2-2 with a maximum sinusoidal voltage of the electrosurgical unit not exceeding 2.2 kV_p	Irrigation set, Syringe and other Luer connecting accessories, endoscopic accessories labeled for use in a working channel size of (ID) 2.0mm/6.0 Fr or less, monopolar electrocautery tools used with the electrosurgical generators, both of which are certified as compliant with IEC 60601-2-2 with allowable voltage levels of the electrosurgical unit not exceeding the following: • Sinusoidal voltage: 2.2 kV_{pp} • Cut: 1.1 kV_p Coagulation: 2.4 kV_p

Reference Device:

Performance benchmark (comparative) testing was performed against the aScope 4 Cysto (K193095).

Performance Testing:

Performance testing has been completed to demonstrate that the proposed CFlex Cystoscope and CystoView Monitor meet the safety and performance requirements established in the design specifications. Comprehensive verification and validation testing included the following:

- System Verification testing including Articulation performance, Irrigation performance, Working Channel performance, High frequency tool activation compatibility performance
- Software Verification testing according to IEC 62304
- Electrical Safety according to IEC 60601-1 and IEC 60601-2-18
- Electromagnetic Compatibility according to IEC 60601-1-2
- Optical performance testing including ISO 8600-1, ISO 8600-3 (Field of View and Direction of View), ISO 8600-4, Sharpness and Depth of Field, Geometric distortion, Color Performance, Noise Performance, Dynamic Range, Image Intensity Uniformity, Resolution
- Photobiological safety according to IEC 62471
- Biocompatibility according to ISO 10993-1 including tests for: Cytotoxicity, Irritation, Sensitization, Material-mediated Pyrogenicity and Acute Systemic Toxicity
- Sterilization validation according to ISO 11135
- Transportation Study according to ASTM D4169
- Stability study to document shelf life according to ASTM F1980
- Sterile Packaging Integrity Testing according to ISO 11607-1
- Cleaning Validation Testing
- Design Validation according to IEC 62366-1

Results: All testing resulted in acceptance criteria passed.

Comparative Testing:

Comparative testing that was performed against the reference device included the following:

- Field of View
- Resolution (MTF/CTF)
- Depth of Field
- Signal to Noise Ratio
- Geometric Distortion
- Image Intensity Uniformity
- Color performance.

Results: The CFlex and CystoView were functionally equivalent to or better than the reference device.

Summary of Clinical Tests:

The CFlex Cystoscope and CystoView Monitor, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

Conclusion:

The information in this 510(k) Premarket Notification demonstrates that the proposed CFlex Single-Use Cystoscope and CystoView Monitor is substantially equivalent to the previously-cleared predicate Ambu aScope 5 Cysto HD and aView 2 Advance Gen. 2 Monitor with respect to safety, effectiveness, and performance.