March 27, 2026

Boston Scientific Corporation
Spencer Duncan, RAC
Principal Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, MA 01752

Re: K251273
Trade/Device Name: Asurys™ Fluid Management System
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, LJH
Dated: March 23, 2026
Received: March 23, 2026

Dear Spencer Duncan:

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,

Reginald K. Avery -S

for
Jason R. Roberts, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251273

Device Name
Asurys™ Fluid Management System

Indications for Use *(Describe)*
The Asurys™ Fluid Management System is intended for use in conjunction with an endoscope to provide irrigation and distention within endourological procedures.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter Information

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Primary Contact Person: Spencer Duncan, +1 (612) 428-1123, spencer.duncan@bsci.com

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Date of 510(k) Summary Preparation: March 27th, 2026

Device Information

Trade Name: Asurys™ Fluid Management System

Model Numbers: M0067974000 (Asurys Fluid Management System) and M0067971010 (Asurys Single-Use Inflow Tubing Set)

Classification Regulation: 884.1700 Hysteroscopic Insufflator

Regulatory Class: Class II

Primary Product Code: HIG (Insufflator, Hysteroscopic)

Secondary Product Code: LJH (System, Irrigation, Urological)

Predicate Device(s)

Predicate Device: Thermedx FluidSmart (K172048)

Reference Device: Endomat Select (K201355)

The predicate and reference devices have not been subject to a design related recall.

Device Description

The Asurys Fluid Management System (FMS) is a multi-functional system for use in a healthcare facility. This device is used during endourological procedures to manage fluid delivery to the patient. This system is comprised of an electromechanical console (capital unit) and a single-use sterile cassette and scope line (also known as Single-Use Device or SUD). The cassette works with the capital unit to apply pressure to the irrigation fluid being used in endourological procedures. Irrigation fluid from a standard source is pumped through a disposable inflow tubing set. The fluid is then delivered through a separate urological endoscope and into the patient's urinary tract.

The subject device is compatible with the following fluids:

- Saline (0.9%)
- Sterile water
- Glycine (1.5%)
- Mannitol (5%)
- Sorbitol (3%)
- Mannitol/Sorbitol (0.54%/2.7%)
- Glucose (5%)

The Asurys FMS supports irrigation across a range of urological procedures, including Ureteroscopy (URS), Percutaneous Nephrolithotomy (PCNL), cystoscopy, and Benign Prostatic Hyperplasia (BPH) procedures. For each procedure type, the physician can utilize the system in **Standalone mode**, compatible with various urological endoscopes. In this mode, the physician sets a desired pump pressure which is maintained by the Asurys FMS through its software-controlled peristaltic pump.

When used with a LithoVue Elite Single-Use Digital Flexible Ureteroscope, the physician can use the Asurys FMS in **LithoVue Elite (LVE) mode** for URS and PCNL procedures. In this mode, the LithoVue Elite's StoneSmart Connect console is connected to the Asurys FMS console, allowing the physician to use the LithoVue Elite scope buttons to control the irrigation settings and also to initiate an on-demand fluid flush (low, medium, and high flush options are available). When used with a LithoVue Elite device which has intraluminal pressure (ILP) monitoring, the physician can also regulate fluid flow based on ILP in addition to the pump pressure setting. The physician sets ILP flow limiter and flush limiter settings so that the Asurys FMS limits fluid flow to reduce the occurrence of higher-than-desired ILP. In addition, ClariSee (software feature) automated flow compensation is supported, which enables consistent fluid flow to be maintained while the working channel of the scope is occupied by instrumentation. Automated flow compensation generates

additional pressure (setpoint +150mmHg pump pressure) to maintain the fluid flow when there is more resistance to fluid flow due to the working channel being occupied with surgical tools. This feature is only possible in LVE Mode.

If pressure monitoring data is not available from LithoVue Elite device, then Asurys FMS can operate in **LVE Lite mode**, which allows use of the LithoVue Elite scope buttons to control the irrigation settings and also to initiate an on-demand fluid flush (low and medium flush options available) but without the ILP flow/flush limiters or ClariSee automated flow compensation.

Intended Use

Indications for Use: The Asurys Fluid Management System is intended for use in conjunction with an endoscope to provide irrigation and distention within endourological procedures.

Comparison of the Technological Characteristics

Property	**K251273 (Subject device)**	**K172048 (Predicate device)**	**Comparison**
Indications for Use	The Asurys Fluid Management System is intended for use in conjunction with an endoscope to provide irrigation and distention within endourological procedures.	Intended for irrigation and fluid warming in laparoscopic procedures, and distention, fluid warming, and volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines.	Different
Pressure generation method	Peristaltic pump	Peristaltic pump	Same
Pump use	Irrigation	Irrigation	Same
User interface	Touchscreen	Touchscreen	Same
Maximum pump pressure	Standalone/LVE Lite mode: 300 mmHg	300 mmHg	Different

	LVE mode: 600 mmHg (with high flush, transient)		
Pump pressure range	Standalone and LVE Lite modes: 30 – 300 mmHg LVE mode: 30 – 450 mmHg base flow range and flush feature allows a temporary increase to 600 mmHg	30 – 300 mmHg	Different
Operating mode (irrigation only)	<u>Device configuration mode:</u> Standalone Mode • Cystoscopy • BPH • PCNL • Ureteroscopy LVE/LVE Lite Mode • PCNL • Ureteroscopy	Diagnostic hysteroscopy Operative hysteroscopy Cystoscopy TURBT TURP PCNL Ureteroscopy Arthroscopy Spine Endoscopy	Different
Compatible fluid	Saline (0.9%) Mannitol (5%) Glycine (1.5%) Sterile water Sorbitol (3%) Mannitol/sorbitol (0.54%/2.7%) Glucose (5%)	Saline (0.9%) Mannitol (5%) Glycine (1.5%) Sterile water Ringer's lactate solution	Different
Flush feature	Yes	No	Different
Heating function	No	Yes	Different
Automated control of fluid flow	Yes	Yes	Same

Monitoring of fluid volume delivered	Yes	Yes	Same
Monitoring of fluid deficit	No	Yes	Different
Waste collection	No	Yes	Different

The subject device has the same intended use. As shown in the table above, the indications for use of the subject device are within the indications for use of the predicate device (Thermedx FluidSmart), which is intended for irrigation and fluid warming in laparoscopic procedures and irrigation, distention, fluid warming, and fluid volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic disciplines. Because the Asurys indications for use are within those of the predicate device, the difference in indications do not raise any intended use concerns.

Different technological characteristics between the subject device and the predicate device include maximum pump output pressure, operating modes, compatible fluid, removal of fluid deficit monitoring, waste collection, and fluid warming features, and introduction of the flush feature. The differences between the subject device and predicate device do not raise different questions of safety and effectiveness and their acceptability have been confirmed through performance testing.

Non-Clinical Testing

Non-clinical testing results, including applicable results per FDA guidance *Hysteroscopic and Insufflators: Submission Guidance for a 510(k)*, confirm substantial equivalence of the Asurys Fluid Management System to the predicate device. Testing included:

- **Biocompatibility**: The Asurys FMS was assessed and tested as appropriate for an externally communicating device making limited tissue contact per ISO 10993-1 (Fifth edition 2018-08) and FDA guidance *Use of International Standard ISO 10993-1*. This included testing the single-use inflow tubing set for cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), irritation (ISO 10993-23:2021), acute systemic toxicity (ISO 10993-11:2017), and material-mediated pyrogenicity (ISO 10993-11:2017).

- **Sterility**: The radiation dose used to sterilize the Asurys single-use inflow tubing set was validated per ISO 11137-1 (First edition 2006-04-15) and ISO 11137-2 (Third edition 2013-06) to ensure a sterility assurance level of 10^{-6} or better.

- **Electromagnetic Compatibility (EMC)**: Asurys FMS was assessed and tested per IEC 60601-1-2 (Edition 4.1 2020-09), IEC 60601-2-2:2017 (Annex BB), and FDA guidance *Electromagnetic Compatibility (EMC) of Medical Devices*. Emissions and immunity testing was performed for Asurys FMS in both Standalone and LVE modes in the worst-case clinical scenarios/settings. This EMC testing established that Asurys FMS will maintain its basic safety and essential performance and will not interfere with other equipment in its intended use environment.

- **Electrical Safety**: Electrical safety of the Asurys FMS was assessed and tested per IEC 60601-1 (Edition 3.2 2020-08), IEC 60601-1-6: 2020, and IEC 60601-2-18: 2009.

- **Software**: Asurys FMS software was validated and verified per FDA guidance *General Principles of Software Validation*. The system performance testing demonstrated the Asurys FMS software successfully displays the GUI and user notifications, responds to user inputs for fluid controls, connects and exchanges information with LVE software (in LVE/LVE Lite modes), responds to the pump pressure/ILP, transitions between modes, saves/exports logs of procedure information, displays tubing set installation/fluid bag status, manages tubing set priming, performs sensor calibrations, monitors for and reacts to errors, and manages user profiles.

- **Cybersecurity**: Asurys FMS was assessed and tested per FDA guidance *Cybersecurity in Medical Devices*: *Quality System Considerations and Content of Premarket Submissions*. This included threat modeling with the STRIDE methodology and multiple rounds of penetration testing to identify, assess, and mitigate vulnerabilities to cybersecurity attacks/failures.

- **Packaging Integrity/Simulated Shipping Distribution Validation**: The single-use inflow tubing set packaging (sterile barrier) was tested to confirm sterile barrier integrity, tray seal strength, shelf carton integrity, aseptic presentation, label adhesion/legibility, and fluid path protection during procedure setup. The console packaging (not a sterile barrier) was also tested to confirm label adhesion/legibility, packaging integrity, and protection of the Asurys console after environmental and distribution conditioning. Transport validation of the devices is provided. The methods used in testing comply with the following standards:
  - ASTM D4169-22: Standard practice for performance testing of shipping containers and systems
  - ASTM D4332-22: Standard practice for conditioning containers packages or packaging components for testing
  - ASTM F2096-11: Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test)
  - ASTM F1886/F1886M-16: Standard test method for determining integrity of seals for flexible packaging by visual inspection
  - ASTM F88/F88M-23: Standard test method for seal strength of flexible barrier materials
  - ASTM D5276 (2019): Standard Test Method for Drop Test of Loaded Containers by Free Fall
  - ASTM D6344 (2017): Standard Test Method for Concentrated Impacts to Transport Packages

- **Shelf Life**: After accelerated aging per ASTM F1980-21 representative of its shelf life (1 year), the single-use inflow tubing set was tested for both performance and packaging sterility. The same design requirements as the baseline single-use inflow tubing set performance testing and baseline packaging testing (both described in the bullets above) were evaluated on the aged devices, establishing that the aged devices continue to perform as designed and remain sterile within the aged packaging.

- **Single-Use Inflow Tubing Set Performance**: Asurys single-use inflow tubing set performance was tested to verify that design requirements were met in the worst-case scenario.

- **Asurys System/Console Performance**: Performance of the subject device was evaluated to verify that design requirements for Standalone, LVE Lite, and LVE mode configurations for applicable cystoscopy, BPH, PCNL, and ureteroscopy modes were met. This included testing of:
    - Pump pressure accuracy
    - Fluid flow acceleration/deceleration
    - Maximum flow rate
    - Maximum pressure limits
    - Fluid bag weight sensor accuracy
    - Electrical sensor accuracy
    - Flow/Flush Limiter functionality
    - Pump pressure limitation
    - ClariSee flow compensation feature functionality
    - User interface/software functionality
    - Fluid delivered/low fluid display functionality
    - Tubing set installation
    - Priming functionality

- **Comparative Performance**: The ILPs and flow rates produced by Asurys FMS were tested in a bench model against those produced by marketed fluid management devices to establish substantial equivalence. Specifically, Asurys FMS base flow (no flush) was compared to that of the predicate device across the range of Asurys Standalone mode and LVE mode parameters. Then, to evaluate the addition of the Asurys FMS flush feature, the maximum Asurys flush was compared to that possible from a manual irrigation device to establish comparability of the flush ranges. Finally, the additional Asurys FMS flush feature was also compared to that of the reference device to demonstrate comparability of the electronically controlled flush controls. Collectively, this testing showed that ILPs and flow rates generated by Asurys FMS under clinically relevant conditions are similar to those generated by currently marketed urological irrigation devices.

Conclusion

The conclusion drawn from the non-clinical testing demonstrate that the subject device is as safe and effective as the predicate device and is therefore substantially equivalent to the predicate device.