Bloom Surgical, Inc.
% Roshana Ahmed
Principal Consultant
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

October 29, 2026

Re: K263459
Trade/Device Name: Swics™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 28, 2026
Received: September 28, 2026

Dear Roshana Ahmed:

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.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.10.29 21:10:52 -04'00'

Colin Chen
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K263459

Device Name

SWICS™

Indications for Use *(Describe)*

SWICS™ is intended to clean the lens of a laparoscope during laparoscopic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date Prepared: October 28, 2026

I. Contact Details (21 CFR 807.92(a)(1))

Applicant Name	Bloom Surgical Inc.
Applicant Address	15 Mario Capecchi Dr. Salt Lake City, UT 84108 United States
Applicant Contact Telephone	801-885-8633
Applicant Contact	Jacob Sheffield
Applicant Contact Email	jacob@bloomsurgical.com
Correspondent Name	QUARAS, LLC
Correspondent Address	2101 Camino Rey Fullerton, CA 92833 United States
Correspondent Contact Telephone	657-248-7361
Correspondent Contact	Roshana Ahmed
Correspondent Contact Email	rahmed@quarasconsulting.com

II. Device Name (21 CFR 807.92(a)(2))

Device Trade Name	SWICS™
Common Name	Endoscope and accessories
Classification Name	Laparoscope General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ

III. Legally Marketed Predicate Devices (21 CFR 807.92(a)(3))

Predicate 510(k)	Predicate Trade Name	Product Code
K260710	Clear-Vu System	OCT
K200228	ClearCam System	GCJ

IV. Device Description (21 CFR 807.92(a)(4))

SWICS™ is a sterile, single-use, disposable laparoscope lens cleaner designed to maintain clear and uninterrupted in-abdomen visualization during minimally invasive surgeries (MIS). Attached to the laparoscope prior to insertion of the device into the laparoscopic port, SWICS™ enables cleaning of the lens directly at the surgical site via use of a sliding trigger. The product features a wiping mechanism combined with a self-contained irrigation system that effectively cleans the lens by removing solid debris and fluids.

SWICS™ is offered in the following configuration:

- 10 mm, 0°; designed to fit 10 mm, 0° laparoscopes and 12 mm trocars

The product is co-packaged with two (2) sterile syringes which are used to transfer the selected cleaning fluid to the SWICS™ reservoir.

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

SWICS™ is intended to clean the lens of a laparoscope during laparoscopic procedures.

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

There are slight differences between the subject and predicate device indications for use statements; however, the differences do not alter the intended use of the subject device when compared to the predicate device. All three devices are laparoscope accessories intended to restore or maintain visualization of the surgical site by cleaning the laparoscope lens during surgical procedures.

VII. Technological Comparison (21 CFR 807.92(a)(6))

The SWICS™, Clear-Vu System (K080613), and ClearCam System (K200228) are all single-use, EO sterilized, laparoscopic accessories that utilize a clear polymer sheath that interfaces with the laparoscope and provides a mechanism to clear the distal lens. The SWICS™ configuration subject of this 510(k) is designed to be compatible with 10 mm laparoscopes and 12 mm trocars. Each device mounts onto the laparoscope by sliding a sheath over the scope until a defined feature arrests motion, and each includes a user-operated interface designed for intra-operative use in the operating room.

The SWICS™ combines two well-established lens-clearing modalities:

- fluid delivery to the distal lens for cleaning similar to the Clear-Vu System (K080613).

- a manual mechanism to physically remove fluid and debris from the lens similar to the ClearCam System (K200228).

The differences between the subject and predicate devices are limited to implementation details of fluid supply/pressurization, wiper power transmission, and certain mounting/securement features:

- Irrigation supply and pressure source
    - The SWICS™ utilizes an internal source to deliver cleaning fluid whereas the Clear-Vu System (K080613) relies on connection to a surgical irrigation system.
- Wiper mechanism and power transmission
    - The SWICS™ provides lens cleaning and clearing via a manual mechanical wiping mechanism whereas the ClearCam System (K200228) provides clearing via a manual wiper actuated by a metallic wire through the sheath.
- Mounting and securing methods
    - The subject and predicate devices mount via sheath placement and are secured to the laparoscope using proximal features (clamps/compression). The SWICS™ is secured to the laparoscope via the light port and the scope body.
- Materials
    - The SWICS™ is manufactured from polymer and metal, consistent but not identical to the materials used in the predicate devices.

The SWICS™ and identified predicate devices have the same intended use and the SWICS™ combines the technological features of the Clear-Vu System (K080613) and ClearCam System (K200228). The technological differences between the subject device and the predicate devices do not raise different questions of safety and effectiveness and non-clinical testing demonstrates that these differences do not alter the safety or performance of the subject device when compared to the predicate devices.

Therefore, the SWICS™ is substantially equivalent to the Clear-Vu System (K080613) and ClearCam System (K200228).

VIII. Non-Clinical Test Summaries and Conclusions (21 CFR 807.92(b))

The following performance data were submitted in support of a demonstration of substantial equivalence:

- Sterilization validation per ISO 11135 and evaluation of EO residuals per ISO 10993-7.
- Shelf-life and packaging validation per ASTM D4169 including package integrity testing per ASTM F2096 and ASTM F88/F88M.

- Biocompatibility
    - An evaluation of biological safety was undertaken in accordance with ISO 10993-1:2025. The following tests were conducted: cytotoxicity per ISO 10993-5:2009, sensitization per ISO 10993-10:2021, irritation per ISO 10993-23:2021, acute systemic toxicity per ISO 10993-11:2017, and material-mediated pyrogenicity per USP <151>.
- Mechanical testing including assessments of cleaning efficacy, impact tests, fatigue and shear tests, loading tests, corrosion, chemical exposure, and thermal effects.

Data from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicate devices.