



February 24, 2026

Swift Medical Inc.
Tenzin Yangzom
VP, Global and Regulatory Affairs
1 King Street W, Suit 4800-355
Toronto, ON M5H 1A1
Canada

Re: K251678

Trade/Device Name: Swift Ray 1

Regulation Number: 21 CFR 878.4550

Regulation Name: Autofluorescence Detection Device For General Surgery And Dermatological Use

Regulatory Class: Class II

Product Code: QJF, FXN

Dated: January 28, 2026

Received: January 28, 2026

Dear Tenzin Yangzom:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

YAN FU-S Digitally signed by YAN FU -S
Date: 2026.02.24 08:51:51
-05'00'

for Tanisha Hithe
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

Indications for Use

510(k) Number (if known)

K251678

Device Name

Swift Ray 1

Indications for Use (Describe)

The Swift Ray 1 is a portable digital imaging device that allow clinicians diagnosing and treating wounds, at the point of care, to:

- i. View and digitally record images of a wound,
- ii. Digitally measure and record the size of the wound
- iii. View and record digital images of fluorescence emitted from the wound when exposed to an excitation light, and
- iv. View and record thermographic images and measure temperature differences within the image using long-wave infrared technology

The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone.

The Swift Ray 1 device should not be used to rule-out the presence of bacteria in a wound.

The Swift Ray 1 does not diagnose or treat skin wounds

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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510K SUMMARY – K251678

Preparation Date: February 20, 2026

Contact Details

Applicant Name: Swift Medical Inc.

Applicant Address: 1 King Street W, Suit 4800-355 Toronto ON M5H 1A1 Canada

Applicant Contact telephone number: 6478645402

Applicant Contact: Tenzin Yangzom

Applicant Contact Email: tenzin@swiftmedical.com

Device Name

Device Trade Name: Swift Ray 1

Common Name: Autofluorescence detection device for general surgery and dermatological use

Classification Name: Autofluorescence Imaging Adjunct Tool For Wounds

Regulation Number: 878.4550

Product Code(s): QJF, FXN

Legally Marketed Predicate Device

Predicate Device Number: K191371

Predicate Device Trade Name: MolecuLight i:X

Product Code: QJF, FXN

Secondary predicate Device

Secondary Predicate Device Number: K131596

Secondary Predicate Device Trade Name: WoundVision Scout

Product Code: FXN

Device Description Summary

The Swift Ray 1 is a portable digital imaging system designed for use by clinicians at the point of care to assist in the assessment and documentation of wounds. The device integrates high-resolution digital imaging, fluorescence imaging, and thermographic imaging to capture visual, fluorescent, and thermal data from wounds.

Clinicians can view, measure, and record wound size, as well as detect fluorescence emitted by tissue when exposed to specific excitation light. When used alongside clinical signs and symptoms, fluorescence imaging with Swift Ray 1 has been shown to increase the likelihood of identifying wounds with bacterial loads greater than 10^4 CFU/gram. Additionally, the device captures thermographic images to support visualization of temperature variations across the wound site. Swift Ray 1 is not intended to diagnose or treat wounds, nor should it be used to rule out the presence of bacteria. It operates in combination with Swift's secure software platform, enabling real-time analysis and EMR-compatible documentation.

Intended Use/ Indications for Use

The Swift Ray 1 is a portable digital imaging device that allow clinicians diagnosing and treating wounds, at the point of care, to:

- i. View and digitally record images of a wound,
- ii. Digitally measure and record the size of the wound
- iii. View and record digital images of fluorescence emitted from the wound when exposed to an excitation light, and
- iv. View and record thermographic images and measure temperature differences within the image using long-wave infrared technology

The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone.

The Swift Ray 1 device should not be used to rule-out the presence of bacteria in a wound.

The Swift Ray 1 does not diagnose or treat skin wounds

Indications for Use Comparison

The Swift Ray 1 and the predicate device, MolecuLight i:X (K191371), have comparable use and application for bacterial fluorescence. The Swift Ray 1 has additional multispectral imaging capabilities that enable thermal imaging, which do not raise additional concerns of safety or effectiveness.

Swift Ray 1 is substantially equivalent to the predicate device, WoundVision Scout (K131596) for the thermal imaging. Each module (thermal and bacterial) operates independently, with separate control mechanisms and distinct output generation.

Technological Comparison

The Swift Ray 1 is substantially equivalent to the predicate device with respect to its indications for use. All other technological characteristics, including intended use, target anatomical sites, patient population, emission wavelengths, working distances, and display features, are comparable to those of the predicate device.

Non-Clinical Testing

In-vitro Culture Bench Plate Testing

Nonclinical bench testing was performed to assess the bacterial fluorescence detection capability of the Swift Ray 1 device in a controlled laboratory setting. The objective was to evaluate whether Swift Ray 1 could detect bacterial fluorescence intensity equivalent and at the same density as the predicate device, the MolecuLight i:X, across a wide range of pathogens and under varying bacterial loads.

In a controlled in vitro study, fluorescence intensity was compared across 24 clinically relevant pathogens (72 strains, 216 images) using Swift Ray1 on different compatible smartphone device configurations versus the predicate device, with testing confirming no statistically significant differences in fluorescence intensity across all three replicate plates ($p = 0.179, 0.628, \text{ and } 0.657$, respectively) and across averaged values ($\chi^2(2) = 0.000, p = 1.000$). A 48-hour time series analysis of *S. aureus* and *E. coli* further demonstrated

concordant fluorescence onset at 36 hours across all devices, aligning with bacterial loads exceeding 10^9 CFU/colony. Across the tested pathogens, there was 100% detection agreement for all red-fluorescent species and consistent specificity for non-fluorescent strains.

This nonclinical test presented clear results that the Swift Ray 1 is substantially equivalent to the MolecuLight i:X for fluorescence-based bacterial detection across clinically meaningful loads.

Cybersecurity:

Swift Ray 1 incorporates cybersecurity controls designed to ensure the confidentiality, integrity, and availability of data. The Swift Ray 1 communicates with a smartphone via Bluetooth Low Energy (BLE). Cybersecurity risks associated with wireless communication, access control, and data transmission have been identified and mitigated as part of a structured cybersecurity risk management program.

These controls support the safe and effective operation of Swift Ray 1 within its intended electromagnetic and clinical use environment.

Swift Medical Inc, develops and maintains Swift Ray 1 in accordance with FDA's guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Software Verification and Validation:

Software verification and validation (V&V) activities were conducted for Swift Ray 1 in accordance with established internal software development and quality procedures consistent with FDA expectations for medical device software. The software verification and validation testing evaluated the performance of Swift Ray 1 software functions and confirmed correct implementation of firmware-controlled features, wireless communication, image acquisition, power management, and error handling. Testing assessed system performance within the intended clinical operating environment, including wireless stability, data integrity, and appropriate device responses.

The Software V&V test results demonstrate that the software component of the Swift Ray 1 performs as intended and supports the safe and effective operation of Swift Ray 1.

Clinical Testing

In a prospective two-site accuracy study of 53 chronic wounds, when Swift Ray 1 fluorescence (FL) imaging was used adjunctively with clinical signs and symptoms (CSS), the combined CSS+FL approach improved diagnostic accuracy from 54.7% (CSS alone) to 79.2% (CSS+FL, $p = 0.004$). CSS+FL had a positive predictive value of 92.6% and negative predictive value of 65.4%, confirming that Swift Ray 1 meaningfully increases the likelihood of identifying wounds with clinically significant bacterial load compared with CSS alone, confirming substantial equivalence to the predicate device, MolecuLight i:X.

In a separate single-site repeatability and reproducibility study including 25 wounds and 600 images, Swift Ray 1 fluorescence imaging showed excellent reliability for both fluorescence detection and hue categorization across users, devices, and smartphone models, with AC1 = 0.935 (95% CI 0.90–0.97) for fluorescence detection and AC1 = 0.947 (95% CI 0.923–0.972) for hue-based categorization. The study also demonstrated high device-to-device and cross-platform agreement, supporting interchangeable use of Swift Ray 1 units and compatible smartphones without materially impacting fluorescence assessment.

Conclusion

The combination of non-clinical and clinical data supports that the Swift Ray 1 is substantially equivalent to the predicate device, MolecuLight:iX (K191371) for its intended use and indications for use. The Swift Ray 1 is also substantially equivalent to the WoundVision Scout (K131596) for thermal imaging.