May 13, 2026

SurgImage Corporation
Vince Chen
Product Manager
4f., No. 183, No. 185, No.187, No 189,4f.-1, No. 185,
5F.,NO. 183,NO. 185,NO.187,NO.189,5F.-1,NO. 185, Gangqian Rd
Taipei City, 11494
Taiwan

Re: K253181
Trade/Device Name: SURGIMAGE SIM 1000H Fluorescence Imaging Platform
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: January 15, 2026
Received: January 15, 2026

Dear Vince Chen:

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,

JESSICA CARR -S

Jessica Carr, PhD
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253181

Please provide the device trade name(s).

SURGIMAGE SIM 1000H Fluorescence Imaging Platform

Please provide your Indications for Use below.

SURGIMAGE SIM 1000H Fluorescence Imaging Platform: Upon intravenous administration and use of ICG (Indocyanine Green) consistent with its approved label, the SIM 1000H System is used with ICG(Indocyanine Green) to perform intraoperative fluorescence angiography. The SIM 1000H System is indicated for use in adult. The SIM 1000H System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures. Upon interstitial administration and use of ICG (Indocyanine Green) consistent with its approved label, the SIM 1000H System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. Upon intradermal administration and use of ICG (Indocyanine Green) consistent with its approved label, the SIM 1000H System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. Submitter

SurgImage Corporation
4F., NO. 183, NO. 185, NO.187, NO 189,、4F.-1, NO. 185,、 5F., NO. 183, NO. 185, NO.187, NO.189,、5F.-1, NO. 185, GANGQIAN RD. TAIPEI CITY 11494 Taiwan

Phone: (+886)928608064
Contact Person: Mr. Vince Chen
Contact Email: vince@surgimage.com.tw
Date Prepared: April 22, 2026

II. Device

Name of Device: SURGIMAGE SIM 1000H Fluorescence Imaging Platform
Common Name: Fluorescence Angiographic System
Classification Name: Angiographic X-Ray System, 21 CFR 892.1600
Regulatory Class: Class II
Product Code: IZI

III. Predicate Device

SPY Portable Handheld Imaging (SPY-PHI) System, K230727
Product Code: IZI

IV. Device Description

The SIM 1000H Fluorescence Imaging Platform is a real-time white-light and near-infrared illumination/ fluorescence imaging system used during surgery. Near-infrared illumination is used for fluorescence imaging using ICG (Indocyanine Green) for the visual assessment of blood flow, tissue perfusion and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. It consists of the Imaging Scope (SIM 100H-PT/PB) and the Medical Imaging Server(SIM 500).

V. Indications for Use

SURGIMAGE SIM 1000H Fluorescence Imaging Platform: Upon intravenous administration and use of ICG (Indocyanine Green) consistent with its approved label, the SIM 1000H System is used with ICG(Indocyanine Green) to perform intraoperative fluorescence angiography. The SIM 1000H System is indicated for use in adult. The SIM 1000H System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures. Upon interstitial administration and use of ICG (Indocyanine Green) consistent with its approved label, the SIM 1000H System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. Upon intradermal administration and use of ICG (Indocyanine Green) consistent with its approved label, the SIM 1000H System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.

Comparison to Predicate: The Indications for Use of the subject device are comparable to those of the predicate device. The main difference is that the predicate device specifically calls out use of the device with a particular ICG product (SPY AGENT GREEN), while the indications of use for the subject device denote use of ICG consistent with its approved label. It is also noted that the intended use population for the subject device includes adults only, while that of the predicate device includes adults and pediatrics. These differences do not raise concerns of safety or effectiveness.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device (SIM 1000H) and the predicate device (SPY-PHI) share the same fundamental technological characteristics. Both include a handheld camera and a processing unit, use near-infrared excitation with indocyanine green (ICG) for fluorescence imaging, and provide white-light illumination for visible imaging. Both capture fluorescence and reflected signals, process them in real time, and output intraoperative images.

Device & Predicate Device(s):	K253181	K230727
General Device Characteristics		
Imaging Modes	White Light, NIR Fluorescence	White Light, NIR Fluorescence
Contrast Agent	ICG	SPY AGENT GREEN (indocyanine green for injection)
Excitation light source	Laser (Class 3R)	Laser (Class 3R)
Excitation wavelength	775 - 810 nm	805 nm
Detection wavelength	825 and 850 nm	830 – 900 nm
Excitation light source power output	40.4 mW/cm²	2 mJ/pulse
Repetition rate	30 pulses/s; 15 pulses/s	20 pulses/s (Overlay mode); 40 pulses/s (SPY mode)
Pulse duration	2 ms	8.33 ms (Overlay mode); 10 ms (SPY mode)

Device & Predicate Device(s):	K253181	K230727
Visible light source	LED	LED
Beam Divergence	48°± 5°	50°± 5°
Image Resolution	1080p	1080p

Note: Comparative performance testing was conducted to confirm equivalent ICG detection despite the differences in imaging specifications (i.e., wavelength, power output, repetition rate, pulse duration) between the subject and predicate devices.

VII. Performance Testing

The device(SIM 1000H) was evaluated for electrical safety, electromagnetic compatibility (EMC), usability, laser safety, performance, and software in accordance with international standards.

1)Electrical Safety: In accordance with AAMI ES60601-1:2005, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021, testing demonstrated compliance with basic safety requirements.

2)Electromagnetic Compatibility (EMC): In accordance with IEC 60601-1-2:2014 + A1:2020, Medical electrical equipment, representative emissions and immunity tests confirmed compliance with EMC requirements.

3)Usability: In accordance with IEC 60601-1-6:2010, AMD1:2013, AMD2:2020, in conjunction with IEC 62366-1:2015, AMD1:2020.

4)Laser Safety: In accordance with IEC 60825-1:2014, confirming compliance with safety requirements for laser products.

5) Performance Testing – Bench: Bench testing was conducted to verify that the device meets design input specifications and defined performance requirements. Furthermore, comparative performance testing was performed between the subject and predicate devices to demonstrate substantial equivalence in ICG imaging performance including assessment of (1) Contrast-to-Noise Ratio as a function of excitation light intensity and fluorescence concentrations at different regions of the imaging field, (2) fluorescence detection depth, and (3) spatial resolution.

6)Software: In accordance with IEC 62304:2006 + AMD1:2015.

All test results met the applicable acceptance criteria.

Note: The device(SIM 1000H) is not patient contacting. Therefore, biocompatibility does not apply.

VIII. Conclusions

The SURGIMAGE SIM 1000H Fluorescence Imaging Platform is the same or similar in intended use and fundamental technological characteristics to the predicate device. The non-clinical data support the safety of the device, and the comparative performance testing demonstrates that the SIM 1000H performs comparably to the predicate device. The combination of these data demonstrates that the subject device is the same or similar, with respect to safety and effectiveness, to the legally marketed predicate device.