April 17, 2025

FLUOPTICS SAS (a Getinge Group Company)
% Barb Smith
Principal Regulatory Affairs Specialist (Getinge)
Getinge Group
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K250455
Trade/Device Name: FLUOBEAM LX Imaging System (FBLX); FLUOBEAM LM Imaging System (FBLM)
Regulation Number: 21 CFR 878.4550
Regulation Name: Autofluorescence Detection Device For General Surgery And Dermatological Use
Regulatory Class: Class II
Product Code: QDG, OWN
Dated: February 18, 2025
Received: February 18, 2025

Dear Barb Smith:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 2025.04.17 16:33:10 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250455

Device Name

FLUOBEAM LX Imaging System (FBLX);
FLUOBEAM LM Imaging System (FBLM)

Indications for Use *(Describe)*

FLUOBEAM LX and FLUOBEAM LM are intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures. Upon intravenous administration and use of an ICG consistent with its approved labeling, the FLUOBEAM LX and FLUOBEAM LM are indicated for use in capturing and viewing fluorescent images for the visualization of vessels, blood flow and tissue perfusion before, during and after organ transplant, plastic, micro- and reconstructive surgeries.

The FLUOBEAM LX and FLUOBEAM LM can also be used to assist in the imaging of parathyroid glands and can be used as an adjunctive method to assist in the location of parathyroid glands due to the auto-fluorescence of this tissue.
Use of the FLUOBEAM LX and FLUOBEAM LM devices are intended to assist, not replace, experienced visual assessment, and biopsy with conventional histopathological confirmation per standard of care. The system is not to be used to confirm the absence of parathyroid tissue or glands and is only to be used to assist in locating visually identified gland/tissues.

Upon interstitial administration and use of ICG consistent with its approved labeling, the FLUOBEAM LX and FLUOBEAM LM are used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved labeling, the FLUOBEAM LX and FLUOBEAM LM are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K250455

Applicant Information:	
Date Prepared:	April 4, 2025
Name:	FLUOPTICS SAS
Address:	44 rue des berges, 38000 Grenoble, France
Phone:	+33 (0)4 85 87 06 60
Contact Person:	Barb Smith, Principal Regulatory Affairs Specialist
Email:	barb.smith@getinge.com
Office:	(583) 370-6101

Device Information:	
Device Trade Name:	FLUOBEAM LX and FLUOBEAM LM
Common Name:	Fluorescence imaging system
Classification Name(s):	Autofluorescence detection device for general surgery and dermatological use
Product Code/ Regulation:	QDG / 21 CFR 878.4550; OWN/ 21 CFR 876.1500
Classification:	Class II

Predicate Device:	
Submitter Name:	FLUOPTICS SAS
Device Trade Name:	FLUOBEAM LX (K233564)
Device Common Name:	Fluorescence imaging system
Classification Name(s):	Autofluorescence detection device for general surgery and dermatological use
Product Code/ Regulation:	QDG / 21 CFR 878.4550
Classification:	Class II

Reference Device:	
Submitter Name:	Visionsense Ltd.
Device Trade Name:	VS3-Iridium System (VS3-IR) (K223020)
Device Common Name:	Near-IR visualization system
Classification Name(s):	Endoscope and accessories.
Product Code/ Regulation:	OWN / 21 CFR 876.1500
Classification:	Class II

Device Description

FLUOBEAM LX and FLUOBEAM LM are imaging systems intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures.

Class 1 infrared laser light is used to excite the fluorescent tissues of parathyroid glands or the ICG or the pafolacianine and illuminate the regions of a patient's body to be observed. A camera inside the optical head captures the fluorescent image that is used to visualize the parathyroid glands or assess the blood vessels and related tissue perfusion. FLUOBEAM LX and FLUOBEAM LM consist of the following components: a hardware part with a camera unit (optical head) linked by a specific cable to a control box and a software part with FLUOSOFT LX or FLUOSOFT LM imaging software. The optical head contains a video camera and light sources (laser and LEDs) and is used by hand. The control box receives the video signal of the fluorescent image from the optical head, it digitizes it and sends it to a computer that outputs it on a display screen and/or records it. Adjustments of the fluorescent image are possible either by the optical head or via the FLUOSOFT LX imaging software and the FLUOSOFT LM imaging software on the computer.

The subject devices FLUOBEAM LX and FLUOBEAM LM have therefore exactly the same principle of operation of the predicate device. Only aesthetic aspects are different between FLUOBEAM LX and FLUOBEAM LM.

This Traditional 510(k) premarket notification of the FLUOBEAM LX and FLUOBEAM LM is to expand the indication for use statement to include the usage in the lymphatic system with the use of an ICG consistent with its approved label.

This Traditional 510(k) premarket notification of the FLUOBEAM LX and FLUOBEAM LM is to expand the indication for use statement to include the additional cleared infrared dye, pafolacianine, for use with infrared imaging.

Indications for Use

FLUOBEAM LX and FLUOBEAM LM are intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures. Upon intravenous administration and use of an ICG consistent with its approved labeling, the FLUOBEAM LX and FLUOBEAM LM are indicated for use in capturing and viewing fluorescent images for the visualization of vessels, blood flow and tissue perfusion before, during and after organ transplant, plastic, micro- and reconstructive surgeries.

The FLUOBEAM LX and FLUOBEAM LM can also be used to assist in the imaging of parathyroid glands and can be used as an adjunctive method to assist in the location of parathyroid glands due to the auto-fluorescence of this tissue.
Use of the FLUOBEAM LX and FLUOBEAM LM devices are intended to assist, not replace, experienced visual assessment, and biopsy with conventional histopathological confirmation

per standard of care. The system is not to be used to confirm the absence of parathyroid tissue or glands and is only to be used to assist in locating visually identified gland/tissues.

Upon interstitial administration and use of ICG consistent with its approved labeling, the FLUOBEAM LX and FLUOBEAM LM are used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved labeling, the FLUOBEAM LX and FLUOBEAM LM are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

Technological Characteristics

The subject devices FLUOBEAM LX and FLUOBEAM LM have the same performance as the predicate device FLUOBEAM LX device cleared in K233564 and is similar to reference device VS3 Iridium System cleared in K223020 by the FDA for commercial distribution in the United States. The subject devices were shown to be the same or similar and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. The subject devices, predicate device and reference device utilize the same mode of imaging – near infrared fluorescence imaging, with ICG and pafolacianine as the imaging agents, used in the hospital operating room.

The introduction of these subject devices FLUOBEAM LX and FLUOBEAM LM raises no new or different issues of safety and effectiveness such that the subject devices FLUOBEAM LX and FLUOBEAM LM are substantially equivalent to the predicate devices.

In addition, it is noteworthy that the reference device VS3-Iridium System (VS3-IR) (K223020) has taken the same indication for use as that taken by this traditional 510(k) for FLUOBEAM LX and FLUOBEAM LM.

	FLUOBEAM LX FLUOBEAM LM 510k pending	FLUOBEAM LX K233564	VS3-Iridium System (VS3-IR) K223020
Class	II	II	II
Product Code	QDG, OWN	QDG	OWN
Regulation Number	21 CFR 878.4550 21 CFR 876.1500	21 CFR 878.4550	21 CFR 876.1500
Light source	Infrared Laser	Infrared Laser	Infrared Laser
Fundamental scientific technology	Emits a Class 1 laser light at a wavelength of 750nm in order to generate fluorescent light in the range 800-900nm	Emits a Class 1 laser light at a wavelength of 750nm in order to generate fluorescent light in the range 800-900nm	Emits a Class 3R laser light at a wavelength of 785nm or 805nm in order to generate fluorescent light in the range 800-850nm

	FLUOBEAM LX FLUOBEAM LM 510k pending	FLUOBEAM LX K233564	VS3-Iridium System (VS3-IR) K223020
Intended Use (From Product Code Description)	As an imaging system used in capturing and viewing fluorescent images	As an imaging system used in capturing and viewing fluorescent images	The VS3-Iridium System is intended to provide real-time visible and near infrared (NIR) fluorescence imaging in both open and minimally invasive procedures.
Working distance	8 – 45 cm	8 – 45 cm	20 – 45 cm
Excitation Light Source Intensity	5.0 ± 0.5 mW/cm² at 20cm	5.0 ± 0.5 mW/cm² at 20cm	6 mW/cm² at 40 cm Max of 47 mW/cm²
Camera	Color CMOS sensor	Color CMOS sensor	Silicon Image Sensor
Contrast agent	ICG, pafolacianine	ICG	ICG, pafolacianine

Performance Data

The FLUOBEAM LX and FLUOBEAM LM were designed and developed by FLUOPTICS in accordance with the applicable requirements and standards to establish performance and safety of the device. The expansion of the indication of the subject device does not change the electrical safety, electromagnetic compatibility, or cleaning from the previous clearance in K233564.
Performance of the FLUOBEAM LX and FLUOBEAM LM with pafolacianine was verified.
Performance of the FLUOBEAM LX and FLUOBEAM LM for visualization of the lymphatic system was verified.
Software validation data was provided for minor included software updates.

Bench testing has been performed to validate the capability of FLUOBEAM LX and FLUOBEAM LM to image ICG for the visualization of the lymphatic system and pafolacianine. These tests consisted of the following:

- In vitro imaging of ICG with different concentrations,
- In vitro imaging of pafolacianine with different concentrations,

These tests showed that the FLUOBEAM LX and FLUOBEAM LM is capable of imaging ICG at different concentrations and pafolacianine at different concentrations.

Additional comparison testing with the reference device (K223020) was conducted to support substantial equivalence in regard to differences in light source and excitation wavelength.

- The FLUOBEAM LX and FLUOBEAM LM was able to visualize similar concentration samples of ICG compared to the reference device, both by analysis of the image contrast (SNR) and by observation of the images.

- The FLUOBEAM LX and FLUOBEAM LM was able to visualize lower concentration samples of pafolacianine compared to the reference device, both by analysis of the image contrast (SNR) and by observation of the images.

Human Factors

Human Factors Report was updated to document the inclusion of the new expanded indication for visualization of the lymphatic system and for use of the device with pafolacianine. An assessment of user profiles, environment of use, training, user interactions with the device and procedure workflow for the new indication were assessed. It was concluded that all these factors remain the same, and identified risks, mitigations and verification was conducted and found acceptable. Therefore, the FLUOBEAM LX and FLUOBEAM LM have been found to be safe and effective for the intended users in the intended use environment for the new indication of use of the subject devices with pafolacianine.

Software Verification and Validation

Software verification and validation testing were updated and conducted. Documentation was provided as recommended by FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff" issued on May 11, 2005 and draft "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on November 4, 2021. The software for this device was considered a "Moderate" level of concern and "Basic Documentation Level", since a malfunction of the device software could lead to a delay in care if the physician were to rely on FLUOBEAM LX or FLUOBEAM LM instead of performing a visual assessment of the perfusion in the interested tissue.

All these tests conducted with FLUOBEAM LX and FLUOBEAM LM are described in the 510(k) submission. The results of these performance evaluations demonstrated that the FLUOBEAM LX and FLUOBEAM LM met the acceptance criteria defined in the product specification, functioned as intended, and performed comparably to the predicate device.

Conclusion

Based on the indications for use, technological characteristics, performance testing, and, comparison to predicate device and reference device, the subject devices FLUOBEAM LX and FLUOBEAM LM have been shown to be as safe, as effective, and to perform as well as the legally marketed predicate device FLUOBEAM LX (K233564) and the legally marketed reference device VS3-Iridium System (VS3-IR) (K223020) as the differences do not raise new questions of safety and efficacy.