



December 15, 2023

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

Re: K233564

Trade/Device Name: FLUOBEAM® LX Imaging System (FB-LX); FLUOBEAM® LX Red Imaging System (FB-LXR)
Regulation Number: 21 CFR 878.4550
Regulation Name: Autofluorescence Detection Device For General Surgery And Dermatological Use
Regulatory Class: Class II
Product Code: QDG
Dated: November 6, 2023
Received: November 6, 2023

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.

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,

Tanisha L. Hithe -S Tanisha L. Hithe -S
2023.12.15
23:42:56 -05'00'
Hithe -S

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)

K233564

Device Name

FLUOBEAM® LX Imaging System (FB-LX);

FLUOBEAM® LX Red Imaging System (FB-LXR)

Indications for Use (Describe)

FLUOBEAM® LX and FLUOBEAM® LX Red 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® LX Red 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® LX Red 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® LX Red 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Premarket Notification Special 510(k) Summary

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

510(k) Number: K233564

Applicant Information:

Date Prepared: December 7th, 2023
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® LX Red
Common Name: Fluorescence imaging system
Classification Name(s): Parathyroid Autofluorescence Imaging Device
Product Code/ Regulation: QDG / 21 CFR 878.4550
Classification: Class II

Predicate Devices:

Submitter Name: FLUOPTICS SAS
Device Trade Name: FLUOBEAM® LX (K190891) and FLUOBEAM LX Red (K230898)
Device Common Name: Fluorescence imaging system
Classification Name(s): Parathyroid Autofluorescence Imaging Device
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): Confocal Optical Imaging
Product Code/ Regulation: OWN / 21 CFR 876.1500
Classification: Class II

Device Description:

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

FLUOBEAM® LX and FLUOBEAM® LX Red 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® LX Red 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.

FLUOBEAM® LX and FLUOBEAM® LX Red enable surgeons to observe fluorescent images of parathyroid glands, blood vessels and related tissue perfusion. Fluorescence can be observed as a result of natural fluorescence of parathyroid glands or as a result of a fluorescent product, indocyanine green (ICG), injected intravenously into patients before the surgery allowing the perfusion assessment.

Class 1 infrared laser light is used to excite the fluorescent tissues of parathyroid glands or the ICG 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® LX Red 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™ LX Red 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™ LX Red imaging software on the computer.

This special 510(k) premarket notification is intended to re-frame the indications for use statement to be consistent with specific indications of legally marketed ICG products, eliminating the need for the co-packaging with ICG.

Indications for Use:

FLUOBEAM® LX and FLUOBEAM® LX Red 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® LX Red 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® LX Red 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® LX Red 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.

Comparison of Technological Characteristics with the Predicate Devices:

There are no changes in technological characteristics in the visualization system hardware, software, or accessories associated with the labeling changes compared to the predicate devices FLUOBEAM® LX device (K190891) and FLUOBEAM LX Red (K230898).

The only change in the system configuration is to update the instructions for use, the indication for use and obsolete the Refill kit for the co-packaging with ICG.

The introduction of these modified devices FLUOBEAM® LX and FLUOBEAM® LX Red raises no new or different issues of safety and effectiveness such that the modified devices FLUOBEAM® LX and FLUOBEAM® LX Red 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 approach as that taken by this Special 510(k), re-frame of the indications for use statement to be consistent with specific indications of legally marketed ICG products, eliminating the need for the co-packaging with ICG.

Performance Data:

No performance data are needed to support the modified indications for use. As noted above, there are no technological changes associated with the proposed labeling changes. Additionally, no new surgical procedures or tissue types are being referenced in the modified indications for use.

Conclusions

The proposed modified devices FLUOBEAM® LX and FLUOBEAM® LX Red are substantially equivalent to the FLUOBEAM® LX and FLUOBEAM LX Red legally marketed under the previously cleared 510(k) clearance.