Fluoptics
% Michael Daniel
President
Daniel & Daniel Consulting, LLC
340 Jones Lane
Gardnerville, Nevada 89460

July 31, 2019

Re: K190891
Trade/Device Name: Fluobeam LX
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: June 27, 2019
Received: July 1, 2019

Dear Michael Daniel:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Neil R.P. Ogden
Assistant Director, THT4A4
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

Section 8. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(K) Number (if known) K190891

Device Name

Fluobeam® LX

◦ Indications for Use *(Describe)*

Fluobeam® LX is intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures. The Fluobeam® LX is indicated for use in capturing and viewing fluorescent images for the visual assessment of blood flow in adults as an adjunctive method for the evaluation of tissue perfusion, perfused organs, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive and organ transplant surgeries.

The Fluobeam® LX 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 device is 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 9. Premarket Notification 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: K190891

Applicant Information:

Date Prepared:	July 30, 2019
Name:	Fluoptics
Address:	7 Parvis Louis Neel, CS 20050 38040 Grenoble Cedex 9, France
Phone:	+33 (0)4 38 78 28 78
Contact Person:	Michael A Daniel, Consultant
Email:	madaniel@clinregconsult.com
Phone Number:	(415) 407-0223
Office:	(775) 392-2970
Facsimile Number:	(610) 545-0799

Device Information:

Device Trade Name:	Fluobeam® LX
Common Name:	Fluorescence imaging system
Classification Name(s):	Parathyroid Autofluorescence Imaging Device
Product Code/ Regulation:	QDG / 21 CFR 878.4550
Classification:	Class II

Predicate Device:

Submitter Name:	Fluoptics
Submitter Address:	7 Parvis Louis Neel CS 20050 – 38040 Grenoble Cedex 9 - FRANCE
Device Trade Name:	Fluobeam 800 Clinic Imaging Device used with Fluocase 800 Control System
Device Common Name:	Fluorescence imaging system
Product Code/ Regulation:	QDG / 21 CFR 878.4550
Classification:	Class II

Device Description:

Fluobeam® LX is an imaging system intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures. This device is indicated for use in capturing and viewing fluorescent images for the visual assessment of blood flow in adults as an adjunctive method for the evaluation of tissue perfusion, perfused organs, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive and organ transplant surgeries.

Fluobeam® LX 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 device is 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 enables surgeons to observe fluorescent images of parathyroid glands, blood vessels and related tissue perfusion. Fluorescence can be observed thanks to natural fluorescence of parathyroid glands or thanks to 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 consists 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 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 on the computer.

The subject device Fluobeam® LX has therefore exactly the same principle of operation of the predicate device. Fluobeam® LX is only a second generation than the predicate Fluobeam® device.

Indications for Use:

Fluobeam® LX is intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures. The Fluobeam® LX is indicated for use in capturing and viewing fluorescent images for the visual assessment of blood flow in adults as an adjunctive method for the evaluation of tissue perfusion, perfused organs, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive and organ transplant surgeries.

The Fluobeam® LX 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 device is 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:

The Fluobeam® LX has the same technological characteristics as the predicate device: it emits a Class 1 laser light at a wavelength of 750nm in order to generate fluorescent light in the range 800-900nm. For the Fluobeam® LX device, technical optimizations have been made in order to facilitate the manufacturing process, improve performance in terms of sensitivity and minor design modifications have been implemented.

Bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between the new Fluobeam® LX and the predicate device. Clinical testing was also performed in Europe by independent surgeons who accepted to share the images with Fluoptics to compare the two devices. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and its performance, compared to the predicate device.

The introduction of this new Fluobeam® LX, which is a second generation of the Fluobeam® devices, raises no new or different issues of safety and effectiveness such that the subject Fluobeam® LX device is substantially equivalent to the predicate device.

Performance Data:

Performance and safety testing according to international standards has been performed:

1. Electrical per IEC 60601-1.
2. Electromagnetic Compatibility per IEC 60601-1-2.
3. Laser safety per IEC 60825-1 (Class I laser product).

Bench tests were also carried out to demonstrate equivalence:
-the homogeneity of the excitation illumination pattern;
-the live image quality (spatial resolution and acquisition frame rate);
-the fluorescence sensitivity.

Clinical data were also acquired by independent surgeons to confirm the results of these bench tests. Fluobeam® LX has been used clinically in Europe with no adverse events reported to date.

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

Substantial Equivalence:

The predicate device is the Fluobeam 800 Clinic® Imaging Device with Fluocase 800™ Control System, Fluorescent Imaging System from Fluoptics. This is the first generation of the Fluobeam® devices range. Fluobeam® LX is the second generation of the Fluobeam® devices range.

The intended use, indications for use, and the principles of operation of the Fluobeam® LX and its predicate are the same. Fluobeam® LX and the predicate device have similar technological characteristics and the minor technological and design differences do not raise new or different questions of safety or effectiveness, as confirmed by verification and validation testing described in this 510(k) submission. Both devices function as cameras allowing surgeons to view fluorescence images of blood flow and evaluation of tissue perfusion with the use of indocyanine green (ICG); or visualization of parathyroid glands by autofluorescence.

Summary:

Based upon descriptive information provided, verification and validation testing completed and basic functionality and technological similarities, the Fluobeam® LX is substantially equivalent to the cited predicate device.