

Section 8. 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: K132475

Applicant Information:

Date Prepared: May 7, 2014
 Name: Fluoptics
 Address: 7 Parvis Louis Neel, CS 20050
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 Phone: +33 (0)4 38 78 37 97
 Contact Person: Michael A Daniel, Consultant
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Device Information:

Device Trade Name: Fluobeam 800 Clinic® Imaging Device with Fluocase 800™
 Control System
 Common Name: Fluorescence imaging system
 Classification Name(s): Angiographic X-Ray System
 Product Code/Regulation: OWN / 21 CFR 876.1500
 Classification: Class II

Predicate Device:

Submitter Name: Hamamatsu Photonics K.K.
 Submitter Address: 812 Joko-cho, Higashi-ku, Hamamatsu City, 431-3196, JAPAN
 Device Trade Name: PDE™
 Device Common Name: Fluorescent Angiographic System
 Product Code/Regulation: IZI / 21 CFR 892.1600
 Classification: Class II

Device Description:

The Fluobeam 800 Clinic® Imaging Device is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive and organ transplant surgeries. The Fluobeam 800 Clinic® Imaging Device is intended for intraoperative visual assessment of blood vessels and related tissue perfusion, by enabling surgeons to observe fluorescent images of blood vessels and related tissue

perfusion. Indocyanine green (ICG) is injected intravenously into patients. Class I infrared laser light is used to excite the fluorescence of ICG and illuminate the regions of a patient's body to be observed. A charge coupled device (CCD) camera captures the fluorescent image that is used to assess the blood vessels and related tissue perfusion. The Fluobeam 800 Clinic® Imaging Device consists of the following components: Fluobeam® camera unit and Fluocase 800 Control System. The Fluobeam® Camera Unit contains a CCD camera and laser sources and is used either by hand or attaching it to a mechanical arm. The Controller System receives the video signal of the fluorescent image from the Camera Unit, 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 Camera Unit or via a graphic interface on the computer.

Indications for Use:

As an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive and organ transplant surgeries.

Performance Data:

The following electrical, performance, and clinical tests have been conducted with the Fluobeam 800 Clinic® Imaging Device and are described in the 510(k) submission. All tests demonstrate that the device functions as intended.

1. Electrical per IEC 60601-1.
2. Electromagnetic Compatibility per IEC 6060 1-1-2.
3. Laser safety per IEC 60825-1 (Class I laser product).

The Fluobeam 800 Clinic® Imaging Device has been sold and used clinically in Europe with no adverse events reported to date. A review of the published literature concludes that the device worked as intended by safely assessing the blood flow and related tissue perfusion during surgeries.

Substantial Equivalence:

The predicate device is the Hamamatsu Photonics K.K., PDE Fluorescent Angiographic System. The intended use, indications for use, and the principles of operation of the Fluobeam 800 Clinic® Imaging Device and its predicate device are the same. The Fluobeam 800 Clinic® Imaging Device and the predicate devices 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 the 510(k) submission. All devices function as cameras allowing surgeons to view fluorescent images of blood flow and evaluation of tissue perfusion with the use of indocyanine green (ICG).

Summary:

Based upon descriptive information provided, verification and validation testing completed and basic functionality and technological similarities, the Fluobeam 800 Clinic® Imaging Device is substantially equivalent to the cited predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

Fluoptics
% Mr. Michael A. Daniel
Daniel & Daniel Consulting, LLC
8 Snowberry Court
Orinda, California 94563

Re: K132475

Trade/Device Name: Fluobeam 800 Clinic® Imaging Device
with Fluocase 800™ control system

Regulation Number: 21 CFR 876.1500

Regulation Name: Confocal optical imaging

Regulatory Class: Class II

Product Code: OWN

Dated: April 1, 2014

Received: April 4, 2014

Dear Mr. 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. 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

Page 2 – Mr. Michael A. Daniel

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar -S

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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132475

Device Name
Fluobeam 800 Clinic® Imaging Device with Fluocase 800™ control system

Indications for Use (Describe)
As an imaging system used 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, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive and organ transplant surgeries.

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)

Neil R Ogden -S

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