K110480

JAN 13 2012

510(k) Summary
PDE

Submitter Name: Hamamatsu Photonics K.K.

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Date Prepared: February 17, 2011

Device Trade Name: PDE

Device Common Name: Fluorescent Angiographic System

Product Code: IZI

Classification: Class II

Predicate Devices: Novadaq Technologies Inc.'s SPY Imaging System SP2000 (K063345) and SPY Fluorescent Imaging System SP2001 (K073130)

Device Description: The PDE 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 PDE 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. Infrared light-emitting diodes (LEDs) are 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 PDE consists of the following components: Camera Unit, Controller, and Remote Controller. The Camera Unit contains a CCD camera and LED light sources and is used either by hand or attaching it to a mechanical arm. The Controller receives the video

signal of the fluorescent image from the Camera Unit and outputs the processed fluorescent image to the external video monitor and recorder. Adjustments of the fluorescent image are possible either by the Camera Unit or the Remote Controller.

Intended Use: The PDE 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.

Performance data: The following electrical, performance, and clinical tests have been conducted with the PDE 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 60601-1-2.

3. Light Emitting LED Product per IEC 60825-1 (Class1 LED product).

4. The PDE has been sold and used clinically for 5 years in Japan without any adverse events. 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 devices are Novadaq Technologies Inc.'s SPY Imaging System SP2000 (K063345) and SPY Fluorescent Imaging System SP2001 (K073130). The intended use, indications for use, and the principles of operation of the PDE and its predicate devices are the same. The PDE and the predicate devices have similar technological characteristics, and any minor differences do not raise different questions of safety or efficacy, as confirmed by Hamamatsu's testing and validation activities described in this 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. Further, the PDE is at least as safe and effective as the predicate devices. This leads to the conclusion of substantial equivalence between the PDE and SPY Imaging System SP2000 and SPY Fluorescent Imaging System SP2001. The Substantial Equivalence Comparison chart is found in Section XIII.

Page (2) of (2)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN 13 2012

Hamamatsu Photonics, K.K.
% Hyman, Phelps & McNamara, P.C.
Mr. Jeffrey K. Shapiro
700 13th Street, N.W., Suite 1200
Washington, District of Columbia 20005

Re: K110480
Trade/Device Name: PDE
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: OWN
Dated: January 11, 2012
Received: January 12, 2012

Dear Mr. Shapiro:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110480

Device Name: PDE

Indications for Use:

The PDE 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation
Center for Devices and Radiological Health
510(k)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110480

Page (1) of (1)