DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 11, 2017

Novadaq Technologies Inc.
Jen Pendlebury
Director of Regulatory Affairs
8329 Eastlake Drive
Unit 101
Burnaby, British Columbia
V5A 4W2 CA

Re: K162885
Trade/Device Name: Spy Phi Open Field Handheld Fluorescence Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: October 14, 2016
Received: October 17, 2016

Dear Jen Pendlebury:

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 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162885

Device Name
SPY Phi Open Field Handheld Fluorescence Imaging System

Indications for Use *(Describe)*

The SPY Phi Open Field Handheld Fluorescence Imaging System is an imaging system used in capturing and viewing fluorescence 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 surgical procedures.

The SPY Phi Open Field Handheld Fluorescence Imaging System is intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during gastrointestinal surgical procedures.

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.

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Section 5 - 510(k) Summary

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

Trade Name: SPY PHI Open Field Handheld Fluorescence Imaging System

Device Model Number: HH9000

Common Name: Fluorescence Angiographic System

Regulation: 21 CFR § 892.1600

Classification Name: Angiographic X-Ray System

FDA 510(k) Review Panel: General and Plastic Surgery

Product Code: OWN

Classification: Class II

Manufacturer:
Novadaq Technologies Inc.
8329 Eastlake Drive, Unit 101
Burnaby, British Columbia
Canada, V5A 4W2

Contact Name:
Jen Pendlebury
Director of Regulatory Affairs
Tel: (905) 629-3822 Ext. 205
Fax: (905) 247-0656

Date 510(k) Summary Prepared: January 5, 2017

Predicate Devices:

Device Trade Name:	PDE-Neo
Submitter Name:	Hamamatsu Photonics, K.K.
Device Common Name:	Fluorescence Angiographic System
Product Code/Regulation:	IZI/ 21 CFR § 892.1600
Classification:	Class II
Device Trade Name:	Fluobeam 800 Clinic® Imaging Device with Fluocase 800™ control system
Submitter Name:	Fluoptics
Device Common Name:	Fluorescence Imaging System
Product Code/Regulation:	OWN/21 CFR 876.1500
Classification:	Class II
Device Trade Name:	SPY Imaging System (SP2000) – K063345; SPY Intra-operative Imaging System (SP2001) - K100371
Submitter Name:	Novadaq Technologies Inc.
Device Common Name:	Fluorescence Angiographic System
Product Code/Regulation:	IZI/ 21 CFR § 892.1600
Classification:	Class II

Device Description:

The SPY PHI HH9000 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 gastrointestinal surgeries.

The SPY PHI HH9000 consists of the following components: an Open Field Handheld Imaging Head (HH9030), Light Guide (PC9004), and the Video Processor/Illuminator (VPI) (PC9001).

Indocyanine green (ICG) is injected intravenously into the patient. The Imaging Head may be either handheld or attached to a mechanical arm and provides illumination of the regions of a patient's body to be observed with near infrared laser light to excite ICG fluorescence. Alternatively, the Imaging Head provides white light illumination of the regions of a patient's body to be observed for color imaging.

A CMOS camera in the Imaging Head captures the fluorescent image under laser illumination or a color image under white light illumination. The VPI receives the video signal from the Imaging Head and processes and outputs the video image to a medical grade video monitor and/or video recorder. Adjustments to the operation of SPY PHI are possible through switches at either the Imaging Head or the VPI.

Indications for Use for the SPY PHI System:

"The SPY PHI Open Field Handheld Fluorescence Imaging System is an imaging system used in capturing and viewing fluorescence 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 surgical procedures."

"The SPY PHI Open Field Handheld Fluorescence Imaging System is intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during gastrointestinal surgical procedures."

Summary of Technological Characteristics of the SPY PHI System and Predicate Devices:

SPY PHI and the predicate devices – PDE-Neo, Fluobeam 800 Clinic® Imaging Device with Fluocase 800™ control system, and the SPY Intra-operative Imaging System, have very similar technological characteristics. In addition, SPY PHI utilizes the following existing components of the PINPOINT Endoscopic Fluorescence Imaging System (FDA 510(k) cleared under K150956): the VPI (PC9001), including software and Light Guide Cable (PC9004).

SPY PHI and the predicate devices rely on near infrared fluorescence imaging for the visualization of blood flow and tissue perfusion during surgical procedures. Each of the devices contain a camera unit, a light source, and a video processor and controller, using ICG imaging agent to achieve fluorescence imaging. Upon injection of the imaging agent (ICG), absorption of laser light causes excitation of ICG which is followed by emission of near infrared fluorescence which is acquired by the camera unit as an image of the blood vessels and related tissue perfusion. The resulting images are displayed on a video monitor.

Performance Data:

Non-Clinical Performance Testing of the SPY PHI System

SPY PHI was designed and developed by Novadaq Technologies Inc. (NOVADAQ), in accordance with the applicable requirements and standards to establish performance and safety of the device. The device's safety and performance were verified by tests conducted by NOVADAQ and accredited third party laboratories.

SPY PHI was tested and determined to be in conformance with IEC 60601-1:2006 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*, IEC 60601-1-2 (3rd edition) and IEC 60825:2007 *Safety of laser products -- Part 1: Equipment classification and requirements.*

An assessment of the SPY PHI system software was conducted to demonstrate conformance with the applicable requirements of IEC 62304:2006 *Medical device software – Software life-cycle processes.* It has been demonstrated that all processes and activities necessary for the safe design and maintenance of SPY PHI software are performed in accordance with the standard.

Animal Testing – Validation Data

Animal studies, using a porcine model, were conducted to assess the suitability of the design requirements of SPY PHI to meet user needs and evaluated the in vivo fluorescence imaging capability of SPY PHI in the visualization of blood flow and tissue perfusion in reconstructive and gastrointestinal surgical procedures. The results of these studies support the proposed indications for use for the SPY PHI system.

Conclusions & Summary of Substantial Equivalence

Based on the information submitted in this premarket notification, and based on the technological characteristics, principle of operation, intended use, environment of use, and indications for use, SPY PHI has been determined to be substantially equivalent to the predicate devices, the PDE-Neo (K133719), Fluobeam 800 Clinic® Imaging Device with Fluocase 800™ control system (K132475), and the SPY Intra-operative Imaging System (K063345 and K100371).

Any technological and design differences between SPY PHI and the predicate devices do not raise additional questions of safety or effectiveness.