Novadaq Technologies ULC. (now a part of Stryker)
Agatha Szeliga
Regulatory Affairs Manager
8329 Eastlake Drive, Unit 101
Burnaby, V5A 4W2 Ca

November 15, 2019

Re: K192174
Trade/Device Name: SPY Portable Handheld Imaging (SPY-PHI) System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: August 9, 2019
Received: August 12, 2019

Dear Agatha Szeliga:

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, MS
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT5: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192174

Device Name
SPY Portable Handheld Imaging (SPY-PHI) System

Indications for Use *(Describe)*

Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older.

The SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive 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.

Subject Device Trade Name: SPY Portable Handheld Imaging (SPY-PHI) 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 ULC. (now a part of Stryker)
8329 Eastlake Drive, Unit 101
Burnaby, British Columbia
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Contact Name:
Agatha Szeliga
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Date 510(k) Summary Prepared: August 8, 2019

Predicate Device(s) Information:

Predicate Device Trade Name	SPY Portable Handheld Imaging (SPY-PHI) System	SPY Elite Intraoperative Perfusion Assessment System
510(k) Number	K190729; K162885	K182907
Submitter/510(k) Holder Name	Novadaq Technologies ULC. (now a part of Stryker)/ Novadaq Technologies Inc.	Novadaq Technologies ULC. (now a part of Stryker)
Classification Name	Angiographic X-Ray System	Angiographic X-Ray System
Product Code and Regulation	OWN; 21 CFR § 892.1600	IZI; 21 CFR § 892.1600
Classification	Class II	Class II

Device Description:

The SPY-PHI System 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 for use in imaging during various surgical procedures.

The SPY-PHI System consists of the following main components: Imaging Head/ Imager (HH9030) with an integrated light guide cable 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 the SPY-PHI System are possible through switches at either the Imaging Head or the VPI.

Indications for Use for the SPY-PHI System:

Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY-PHI System used is indicated for use in adult and pediatric patients one month of age and older.

The SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.

Comparison of the Indications for Use of the Subject Device and Predicate Devices:

Subject Device **SPY Portable Handheld Imaging (SPY-PHI) System**	**Predicate Device** **SPY Portable Handheld Imaging (SPY-PHI) System** (K190729)	**Predicate Device** **SPY Portable Handheld Imaging (SPY-PHI) System** (K162885)	**Predicate Device** **SPY Elite Intraoperative Perfusion Assessment System** (K182907)
Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older. The SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.	Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN 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 System is used with SPY AGENT™ GREEN to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion before, during and after gastrointestinal surgical procedures.	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.	Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for Injection, USP), the SPY Elite System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography. The SPY Elite System used with SPY AGENT™ GREEN is indicated for use in adult and pediatric patients one month of age and older. The SPY Elite System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgeries.

Comparison of Device Characteristics of the Subject Device and the Predicate Devices:

Feature	Subject Device	Predicate Devices	
	SPY Portable Handheld Imaging (SPY-PHI) System	**SPY Portable Handheld Imaging (SPY-PHI) System**	**SPY Elite Intraoperative Perfusion Assessment System**
510(k) Holder/ Manufacturer	Novadaq Technologies ULC. (now a part of Stryker)	Novadaq Technologies ULC. (now a part of Stryker)/ Novadaq Technologies Inc.	Novadaq Technologies ULC. (now a part of Stryker)
Submission Reference	Current Submission	K190729; K162885	K182907
Decision Date	Current Submission	04/19/2019; 01/11/2017	01/23/2019
Combination Product	Yes	Yes	Yes
Product Code	OWN	OWN	IZI
Regulation Number	21 CFR 892.1600	21 CFR 892.1600	21 CFR 892.1600
Device Classification Name	System, X-Ray, Angiographic	System, X-Ray, Angiographic	System, X-Ray, Angiographic
Intended Use	Near infrared fluorescence imaging for visualization of blood flow and tissue perfusion during surgical procedures	Near infrared fluorescence imaging for visualization of blood flow and tissue perfusion during surgical procedures	Near infrared fluorescence imaging for visualization of blood flow and tissue perfusion during surgical procedures
Operating Principle	Full color visible light and NIR fluorescence video imaging. The 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.	Full color visible light and NIR fluorescence video imaging. The 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.	NIR light from the illumination module in the imaging console is transmitted to the imaging head via fiber-optic cable. The imaging head is positioned over the patient such that the NIR excitation light is emitted and illuminates the area of interest. When the patient is injected with ICG, the ICG binds to the plasma in the blood and travels to the area of interest through the bloodstream. The NIR excitation light emitted by the SPY Elite imaging device causes the ICG to fluoresce. The fluorescence image signal is processed and simultaneously recorded in computer memory and

Feature	Subject Device	Predicate Devices	
	SPY Portable Handheld Imaging (SPY-PHI) System	**SPY Portable Handheld Imaging (SPY-PHI) System**	**SPY Elite Intraoperative Perfusion Assessment System**
			displayed on the video monitors in real time.
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60825-1
Major components	SPY-PHI imager (with integrated light guide cable) and VPI (Video Processor/ Illuminator)	SPY-PHI imager (with integrated light guide cable) and VPI (Video Processor/ Illuminator)	Imaging console with a detector (CCD camera) and signal processing software
Fluorescence excitation source	NIR laser	NIR laser	NIR laser
Environment of Use	Hospital	Hospital	Hospital
Contrast imaging agent	SPY AGENT™ GREEN (Indocyanine green for injection, USP)	SPY AGENT™ GREEN (Indocyanine green for injection, USP); Indocyanine green (ICG)	SPY AGENT™ GREEN (Indocyanine green for injection, USP)

Performance Testing of the SPY-PHI System:

The SPY-PHI System was designed and developed by Novadaq Technologies Inc. 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 (4th 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.

Clinical Summary and Use in Pediatric Patients:

Safety and effectiveness of the SPY-PHI System for its intended use in the visualization of blood flow and tissue perfusion during various surgical procedures was assessed through a series of clinical literature evaluations to support the expansion to the cleared indications for use, including published literature references to support the expansion of existing indications for use to include pediatric patients, one (1) month of age and older.

Efficacy data obtained from published literature showed successful visualization in majority of the studies. Analysis of ICG doses administered to several pediatric subpopulations showed that the effective doses

used in angiographic applications were similar to those administered to adult patients. Based on anecdotal clinical experience, lower doses of ICG may be effective, especially in younger patients and those with lower body weight.

None of the published literature identified anaphylaxis or any other adverse events related to SPY fluorescence imaging with ICG in pediatric patients. Overall the data suggests that there are no differences in safety and efficacy of SPY fluorescence imaging with ICG between pediatric patients (aged 1 month to 21 years) and adult patients.

Conclusion & Summary of Substantial Equivalence

Based on the information presented in this Traditional 510(k) premarket notification, and based on the fundamental scientific technology, technological characteristics, principle of operation, intended use, environment of use, and indications for use, the SPY-PHI System has been determined to be substantially equivalent to the predicate devices, the SPY Portable Handheld Imaging (SPY-PHI) System (FDA 510(k)-cleared in K162885 and K190729) and the SPY Elite Intraoperative Perfusion Assessment System (FDA 510(k)-cleared in K182907)

Any minor technological or design differences between the SPY-PHI System and the predicate devices do not raise any questions related to safety or effectiveness. The proposed additional/expanded indications for use do not raise any issues related to safety or effectiveness for this device-drug combination product.