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

November 5, 2020

Re: K202244
Trade/Device Name: SPY-PHI System with SPY-PHI Fluorescence Assessment Software
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: August 7, 2020
Received: August 10, 2020

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
Assistant Director, Cancer Diagnosis & Treatment Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202244

Device Name
SPY Portable Handheld Imaging (SPY-PHI) System with SPY-PHI Fluorescence Assessment Software

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.

Upon interstitial administration of SPY AGENT™ GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

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-PHI System with SPY-PHI Fluorescence Assessment Software

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: IZI

Classification: Class II

Manufacturer: Novadaq Technologies ULC. (now a part of Stryker)
8329 Eastlake Drive, Unit 101
Burnaby, British Columbia
Canada, V5A 4W2

Contact Name: Agatha Szeliga
Regulatory Affairs Manager
Tel: 604-422-7516
Fax: 604-232-9841

Date 510(k) Summary Prepared: August 5, 2020

Predicate Device(s) Information:

Predicate Device Trade Name	SPY Portable Handheld Imaging (SPY-PHI) System (primary predicate)	SPY Elite Intraoperative Perfusion Assessment System (secondary predicate to support technological differences/ software feature)
510(k) Number	K200737	K182907
Submitter/510(k) Holder Name	Novadaq Technologies ULC. (now a part of Stryker)	Novadaq Technologies ULC. (now a part of Stryker)
Classification Name	Confocal Optical Imaging	Angiographic X-ray System
Product Code and Regulation	OWN; 21 CFR § 876.1500	IZI; 21 CFR § 892.1600
Classification	Class II	Class II
Note: The predicate devices have not been subject to a design-related recall.		

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 provides real-time, white-light and fluorescence imaging during surgical procedures. The system consists of a SPY-PHI imager/imaging head with an integrated light guide cable and a Video Processor/Illuminator (VPI).

Fluorescence imaging with the SPY-PHI System is achieved with the use of a fluorescence imaging agent, namely SPY AGENT™ GREEN (indocyanine green for injection, USP), which is supplied in single-use convenience kits for use in conjunction with the SPY-PHI System during surgical procedures.

During surgical procedures, SPY AGENT™ GREEN is administered to the patient. The SPY-PHI imaging head/imager provides illumination of the regions of a patient's body to be observed with near infrared (NIR) laser light to excite ICG fluorescence. Alternatively, the SPY-PHI imager provides white light illumination of the regions of a patient's body to be observed for color imaging.

The 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. The SPY-PHI System is intended for use by trained healthcare professionals in the operating room.

This Traditional 510(k) premarket notification proposes a modification to the currently 510(k) cleared SPY-PHI System with the addition of a new software feature. The new software feature, referred to as the *SPY-PHI Fluorescence Assessment Software*, will offer real-time relative fluorescence quantification (i.e. relative fluorescence values) and visualization tools (i.e. color maps) on the SPY-PHI device. Addition of this new software feature has no impact on the current intended use of the SPY-PHI System. The *SPY-PHI Fluorescence Assessment Software* is a firmware module installed on the VPI component of the SPY-PHI System for use during open field surgery where fluorescence imaging is used.

The SPY-PHI Fluorescence Assessment Software enables quantification of fluorescence which may be used as an additional intraoperative tool to assist trained healthcare practitioners in the assessment of fluorescence response in tissue during various surgical procedures. The healthcare practitioner retains the ultimate responsibility for making the pertinent diagnosis based on their clinical judgment and standard practices.

Indications for Use of 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 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 interstitial administration of SPY AGENT™ GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

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

	SUBJECT DEVICE	**PREDICATE DEVICE (primary predicate)**	**PREDICATE DEVICE (secondary predicate to support technological differences/ new software feature)**
Name	**SPY Portable Handheld Imaging (SPY-PHI) System with SPY-PHI Fluorescence Assessment Software**	**SPY Portable Handheld Imaging (SPY-PHI) System**	**SPY Elite Intraoperative Perfusion Assessment System**
Company/ 510(k) Holder	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**
Model	HH9000	HH9000	LC3000
510(k) Reference	TBD (current submission)	K200737	K182907
Product Code	IZI	OWN	IZI
Regulation Number	21 CFR 892.1600	21 CFR 876.1500	21 CFR 892.1600
Classification	Class II	Class II	Class II
Combination Product	Yes	Yes	Yes
Device Classification Name	Angiographic X-ray System	Confocal Optical Imaging	Angiographic X-ray System
Intended Use	Near infrared fluorescence imaging for visualization of blood flow and tissue perfusion before, during and after surgical procedures, and intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	Near infrared fluorescence imaging for visualization of blood flow and tissue perfusion before, during and after surgical procedures, and intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	Near infrared fluorescence imaging for visualization of blood flow and tissue perfusion before, during and after surgical procedures.
Indications for Use	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	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	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

	SUBJECT DEVICE	PREDICATE DEVICE (primary predicate)	PREDICATE DEVICE (secondary predicate to support technological differences/ new software feature)
Name	**SPY Portable Handheld Imaging (SPY-PHI) System with SPY-PHI Fluorescence Assessment Software**	**SPY Portable Handheld Imaging (SPY-PHI) System**	**SPY Elite Intraoperative Perfusion Assessment System**
Company/ 510(k) Holder	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**
	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. Upon interstitial administration of SPY AGENT™ GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	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 interstitial administration of SPY AGENT™ GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	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 surgical procedures.
Patient Population	Adult patients and pediatric patients (1 month of age and older)	Adult patients and pediatric patients (1 month of age and older)	Adult patients and pediatric patients (1 month of age and older)
Major Device Components	VPI (Video Processor/Illuminator) with upgraded firmware for the *SPY-PHI Fluorescence Assessment Software* SPY-PHI imager (with integrated light guide cable)	VPI (Video Processor/ Illuminator) SPY-PHI imager (with integrated light guide cable)	Imaging console with a detector and signal processing software
Operating Principle	Full color visible light and NIR fluorescence video imaging. The imaging head	Full color visible light and NIR fluorescence video imaging. The imaging head	NIR light from the illumination module in the imaging console is

	SUBJECT DEVICE	PREDICATE DEVICE (primary predicate)	PREDICATE DEVICE (secondary predicate to support technological differences/ new software feature)
Name	**SPY Portable Handheld Imaging (SPY-PHI) System with SPY-PHI Fluorescence Assessment Software**	**SPY Portable Handheld Imaging (SPY-PHI) System**	**SPY Elite Intraoperative Perfusion Assessment System**
Company/ 510(k) Holder	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**
	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 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.	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 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.	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 displayed on the video monitors.
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
Environment of Use	Operating room	Operating room	Operating room
Fluorescence excitation source	NIR laser	NIR laser	NIR laser
Imaging Modes	• White Light • SPY • Overlay • Color Segmented Fluorescence (CSF) • Color map (raw color map and relative color map)	• White Light • SPY • Overlay • Color Segmented Fluorescence (CSF)	• SPY • Overlay • Color Segmented Fluorescence (CSF)

		SUBJECT DEVICE	PREDICATE DEVICE (primary predicate)	PREDICATE DEVICE (secondary predicate to support technological differences/ new software feature)
Name		**SPY Portable Handheld Imaging (SPY-PHI) System with SPY-PHI Fluorescence Assessment Software**	**SPY Portable Handheld Imaging (SPY-PHI) System**	**SPY Elite Intraoperative Perfusion Assessment System**
Company/ 510(k) Holder		**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**	**Novadaq Technologies ULC. (now a part of Stryker)**
Fluorescence Assessment Features & Tools	**On-screen timer**	On-screen timer (automatic)	Not available	On-screen timer (manual)
	Signal stability indicator	Signal stability indicator (automatic)	Not available	Signal stability indicator (manual)
	Raw color map	Modified Jet Map as overlay on anatomical grayscale image	Not available	Jet Map
	Relative color map	Modified Jet Map as overlay on anatomical grayscale image	Not available	Not available
	Reference value	Available	Not available	Available
	Relative value	Available	Not available	Available
Imaging Agent		SPY AGENT™ GREEN (indocyanine green for injection, USP)	SPY AGENT™ GREEN (indocyanine green for injection, USP)	SPY AGENT™ GREEN (indocyanine green for injection, USP)

Performance Testing of the SPY-PHI System:

The SPY-PHI System was designed and developed in accordance with the applicable requirements and standards to establish performance and safety of the device. The device's safety and performance were verified, including testing conducted by 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 62304:2015 *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.

A design validation study was performed to assess the suitability of the design requirements of the SPY-PHI Fluorescence Assessment Software as part of the SPY-PHI System to meet user needs. The results of the design validation study support the new fluorescence assessment software of the SPY-PHI System.

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 with SPY-PHI Fluorescence Assessment Software has been demonstrated to be substantially equivalent to the predicate devices, the SPY-PHI System (FDA 510(k)-cleared in K200737) and the SPY Elite System (FDA 510(k)-cleared in K182907).

The SPY-PHI System with SPY-PHI Fluorescence Assessment Software intended for intraoperative fluorescence imaging for visualization of blood flow and tissue perfusion before, during and after various surgical procedures, does not raise any issues related to safety or effectiveness for this device when used as instructed.