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

May 21, 2020

Re: K200737
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, IZI, GCJ
Dated: March 20, 2020
Received: March 23, 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 THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200737

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.

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 Portable Handheld Imaging (SPY-PHI) System

Device Model Number: HH9000

Common Name: Fluorescence Angiographic System

Regulation: 21 CFR § 876.1500

Classification Name: Confocal Optical Imaging

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
Canada, V5A 4W2

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

Date 510(k) Summary Prepared: March 16, 2020

Predicate Device(s) Information:

Predicate Device Trade Name	PINPOINT Endoscopic Fluorescence Imaging System (PINPOINT System) (primary predicate for indications expansion)	SPY Portable Handheld Imaging (SPY-PHI) System (secondary predicate)
510(k) Number	K182606	K192174
Submitter/510(k) Holder Name	Novadaq Technologies ULC. (now a part of Stryker)	Novadaq Technologies ULC. (now a part of Stryker)
Classification Name	Laparoscope, General & Plastic Surgery; Angiographic X-ray System	Confocal Optical Imaging
Product Code and Regulation	GCJ; IZI 21 CFR § 876.1500	OWN 21 CFR § 876.1500
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).

SPY AGENT™ GREEN (indocyanine green for injection, USP) 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 SPY AGENT™ GREEN 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 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 the Indications for Use of the Subject Device and Predicate Devices:

Subject Device **SPY Portable Handheld Imaging (SPY-PHI) System**	**Predicate Device** **(primary predicate for indication expansion)** **PINPOINT Endoscopic Fluorescence Imaging System** (K182606)	**Predicate Device** **(secondary predicate)** **SPY Portable Handheld Imaging (SPY-PHI) System** (K192174)
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.	Upon intravenous administration of SPY AGENT™ GREEN (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with SPY AGENT™ GREEN to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography. The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration of SPY AGENT™ GREEN (ICG drug product), the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	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 Device Characteristics of the Subject Device and the Predicate Devices:

Feature	Subject Device	Predicate Devices	
	SPY Portable Handheld Imaging (SPY-PHI) System	**PINPOINT Endoscopic Fluorescence Imaging System**	**SPY Portable Handheld Imaging (SPY-PHI) System**
510(k) Holder/ Manufacturer	Novadaq Technologies ULC. (now a part of Stryker)	Novadaq Technologies ULC. (now a part of Stryker)	Novadaq Technologies ULC. (now a part of Stryker)
Submission Reference	Current Submission	K182606	K192174
Decision Date	Current Submission	11/21/2018	11/15/2019
Combination Product	No	No	Yes
Product Code	OWN	GCJ; IZI	OWN
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500
Device Classification Name	Confocal Optical Imaging	Laparoscope, General & Plastic Surgery; Angiographic X-ray System	Confocal Optical Imaging
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 during surgical procedures, identification of extrahepatic biliary ducts, 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.
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 PINPOINT camera captures the fluorescent image under laser illumination or a color image under white light illumination. The VPI receives the video signal from camera 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.
Safety Standards	IEC 60601-1	IEC 60601-1	IEC 60601-1

Feature	Subject Device	Predicate Devices	
	SPY Portable Handheld Imaging (SPY-PHI) System	**PINPOINT Endoscopic Fluorescence Imaging System**	**SPY Portable Handheld Imaging (SPY-PHI) System**
	IEC 60601-1-2 IEC 60825-1	IEC 60601-1-2 IEC 60825-1 IEC 60601-2-18	IEC 60601-1-2 IEC 60825-1
Major components	VPI (Video Processor/Illuminator) SPY-PHI imager (with integrated light guide cable)	VPI (Video Processor/Illuminator) Camera Light Guide Cable Laparoscopes	VPI (Video Processor/ Illuminator) SPY-PHI imager (with integrated light guide cable)
Imaging Modes	White Light SPY Overlay Color Segmented Fluorescence (CSF)	White Light SPY Overlay Color Segmented Fluorescence (CSF)	White Light SPY Overlay Color Segmented Fluorescence (CSF)
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)	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 62304:2006 *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.

A design validation study was conducted to assess the suitability of the design requirements of the SPY-PHI System to meet user needs and evaluated the in vivo fluorescence imaging capability of SPY-PHI for the visualization of the lymphatic system, including lymphatic vessels and lymph nodes. The results of the validation study support the proposed expanded indications for use for 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 has been demonstrated to be substantially equivalent to the predicate devices, the PINPOINT Endoscopic Fluorescence Imaging System (FDA 510(k)-cleared in K182606) and the SPY Portable Handheld Imaging (SPY-PHI) System (FDA 510(k)-cleared in K192174).

The proposed expanded indications for use of the SPY-PHI System for intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes using SPY AGENT™ GREEN do not raise any issues related to safety or effectiveness for this device when used as instructed.