June 5, 2023

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

Re: K230727
Trade/Device Name: SPY Portable Handheld Imaging (SPY-PHI) System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: March 15, 2023
Received: March 16, 2023

Dear Cara Cahill:

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,

Jessica Carr -S

Jessica Carr, Ph.D.
Acting Assistant Director
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)*
K230727

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.

Upon intradermal administration of SPY AGENT GREEN, the SPY-PHI System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.

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.

510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R Part 807.92(c)

Submitter:

Applicant	Novadaq Technologies ULC (A Part of Stryker) 8329 Eastlake Drive, Unit 101 Burnaby, British Columbia V5A 4W2, Canada
Contact Person	Cara Cahill Manager, Regulatory Affairs Phone: (408) 754-2473 Email: cara.cahill@stryker.com
Date Prepared	May 10, 2023

Subject Device:

Name of Device	SPY Portable Handheld Imaging (SPY-PHI) System
Common or Usual Name	Fluorescence Angiographic System
Classification Name	Angiographic X-Ray System, 21 CFR 892.1600
Regulatory Class	Class II
Product Code	IZI
510(k) Review Panel:	Radiology

Predicate Device:

Predicate Devices	Manufacturer
SPY-PHI System with SPY-PHI Fluorescence Assessment Software (K202244)*	Novadaq Technologies ULC (A Part of Stryker)
SPY Portable Handheld Imaging (SPY-PHI) System (K200737)	Novadaq Technologies ULC (A Part of Stryker)

*primary predicate

Device Description:

The SPY-PHI System is a real-time white-light and near-infrared illumination/ fluorescence imaging system used during open-field surgical procedures. Near-infrared illumination is used for fluorescence imaging using SPY AGENT® GREEN for the visual assessment of blood flow, tissue perfusion and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. It consists of the SPY Portable Handheld Imager/ imaging head with an integrated light guide and camera cable and the Video Processor/ Illuminator. Additionally, SPY-QP Fluorescence Assessment Software is provided as an optional upgrade to the SPY-PHI System that enables relative quantification of NIR fluorescence.

Indications for Use:

Item	Subject Device	Predicate Device
	SPY Portable Handheld Imaging (SPY-PHI) System	**SPY Portable Handheld Imaging (SPY-PHI) System**
Intended Use	Visible white light and near-infrared illumination during open-field surgical procedures.	Same as subject device
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 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 intradermal administration of SPY AGENT GREEN, the SPY-PHI System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.	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 Technological Characteristics with the Predicate Device:

Feature		Subject Device		Predicate Device
		SPY Portable Handheld Imaging (SPY-PHI) System		SPY Portable Handheld Imaging (SPY-PHI) System
Manufacturer		Novadaq Technologies ULC. (a part of Stryker)		Same as subject device
Submission Reference		Current Submission		K202244, K200737
Imaging System Type		Open-Field		Same as subject device
Imaging Modes		White Light Near-Infrared: - Overlay Mode[1] - SPY Mode (Contrast) [1] - SPY Color Segmented Fluorescence (CSF)		Same as subject device
Principles of Operation		Via Imager, light is transmitted through the Light Cable and projected to illuminate the surgical site/ area of interest. The light emitted and reflected from the surgical site/ area of interest (aside from NIR excitation light, which is blocked by an internal rejection filter) is acquired by the Imager, projected onto the image sensor and converted to a digital signal. The digital signal is transmitted via the Camera Cable to the VPI which receives the optical image information, processes the information, and outputs it to digital video.		Same as subject device
System Components		SPY-PHI Imager Video Processor/ Illuminator SPY-QP Fluorescence Assessment Software		Same as subject device
Safety Standards		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60825-1		Same as subject device
Optical Imaging Specifications	Dynamic Range	The user shall be able to visualize SPY AGENT GREEN in physiology applications. The response on the system monitor to the minimum clinically relevant concentration of SPY AGENT GREEN shall be at least 6.9(ΔE), and the system response to the maximum clinically relevant concentration shall be at least twice that at low concentrations.		Same as subject device
	Localization	The user shall be able to visualize SPY AGENT GREEN in anatomy applications. The response on the system monitor shall be at least 10.35 (ΔE) under clinically relevant conditions.		Same as subject device
SPY-PHI Imager		Image Sensor: CMOS image sensor		Same as subject device
Video Processor/ Illuminator		Light Source/ Laser	RGB LEDs Infrared Laser	Same as subject device

Feature	Subject Device		Predicate Device
	SPY Portable Handheld Imaging (SPY-PHI) System		**SPY Portable Handheld Imaging (SPY-PHI) System**
	Laser Safety Class	Class 3R	Same as subject device
	Wavelengths	White Light: 400 nm – 700 nm Near-infrared: 805 nm	Same as subject device
	Imaging Processing/ Video Output	Digital	Same as subject device
	Resolution	1080p (1920x1080)	Same as subject device
	Frame Rate	60 Hz	Same as subject device
Imaging Agent	SPY AGENT GREEN (indocyanine green for injection, USP)		Same as subject device

[1] SPY Mode (Contrast) and Overlay Mode are recommended for use in breast lymphatic mapping.

Performance Testing:

Test	Method	Result
Electromagnetic Compatibility	In accordance with IEC 60601-1-2:2014, Medical electrical equipment, Part 1. General requirements for safety, 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	PASS
Electrical Safety	In accordance with: • IEC 60601-1:2005+A1:2012, Medical electrical equipment, Part 1. General requirements for safety and essential performance; & applicable national deviations • IEC 60601-1-6:2020-07, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance	PASS
Laser Safety	In accordance with IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements	PASS
Usability	In accordance with IEC62366-1:2015, Medical devices -- Part 1: Application of usability engineering to medical devices	PASS
Performance Testing - Bench	In accordance with design input specifications including optical imaging performance specifications	PASS
Software	In accordance with IEC 62304:2006, Medical device software - Software life cycle processes	PASS

Note: The device is not patient contacting. Therefore, biocompatibility does not apply.

Performance Testing - Clinical:

The Novadaq Technologies ULC-sponsored FILM-B Clinical Study was performed under an IDE (G170109), in accordance with 21 CFR 812.

FILM-B was a single-arm, prospective, multi-center, open-label study in subjects with early stage breast cancers with clinically negative nodal status and who were scheduled for surgery that included clinically indicated sentinel lymph node biopsy with technetium 99m radioactive colloid (Tc99m). Subjects received Tc99m the day before or the day of surgery and SPY AGENT GREEN was injected into the identified breast of subjects at the beginning of the operative procedure. All subjects received the injection into a single breast. A total of 152 subjects were enrolled in the study. Lymphatic mapping was performed intraoperatively using the SPY-PHI System and a handheld gamma probe, or the surgeon's visual and palpation examination. The resected tissues were evaluated by histopathology to confirm presence of lymph nodes.

The FILM-B study design resulted in unbiased, quality, reliable and repeatable data for use in the evaluation of the effectiveness and safety of SPY AGENT GREEN and SPY-PHI in identifying lymph nodes during lymphatic mapping and sentinel lymph node biopsy in subjects with early-stage breast cancer. The FILM-B study met both the primary and secondary effectiveness endpoints.

The primary endpoint of the study was assessed by comparison of the proportion of lymph nodes identified by SPY AGENT GREEN and SPY-PHI with the proportion of LNs identified with Tc99m / gamma probe. Among the confirmed lymph nodes identified, 89% were identified

using SPY AGENT GREEN and SPY-PHI, and 66% were identified using Tc99m /gamma probe, a difference of 23% [95% confidence interval 3.67% to 9.48%]; $p<0.0001$.

As a secondary endpoint, the number of subjects with at least one resected, confirmed lymph node detected by SPY AGENT GREEN and SPY-PHI or Tc99m / gamma probe was determined. Both methods identified at least 1 LN in 95% of subjects. Of these, 45% of subjects had lymph nodes detected with SPY AGENT GREEN and SPY-PHI only, 21% of patients had lymph nodes detected with Tc99m /gamma probe only and 11% of patients had lymph nodes detected with neither SPY AGENT GREEN and SPY-PHI or Tc99m gamma probe.

Another secondary endpoint evaluated the effectiveness of SPY AGENT GREEN and SPY-PHI as an intraoperative near-infrared fluorescence visualization tool for delineation and mapping of lymphatic vessels and the identification of lymph nodes. Lymphatic vessel mapping with SPY AGENT GREEN and SPY-PHI aided in the visualization of 99% of lymph nodes identified by SPY AGENT GREEN and SPY PHI. Only 1% of all lymph nodes identified by SPY AGENT GREEN and SPY-PHI were without the visualization of lymphatic vessels/ channels with SPY AGENT GREEN and SPY-PHI.

The safety of SPY AGENT GREEN and SPY-PHI was also evaluated. There were no serious adverse events associated with the use of SPY AGENT GREEN, or adverse device events or unexpected adverse device events associated with the use of SPY -PHI.

The results from the FILM-B study confirm that SPY AGENT GREEN and SPY-PHI is a clinically safe and effective too for the visualization of lymphatic vessels and identification of lymph nodes during lymphatic mapping for breast cancers.

Conclusions:

The SPY Portable Handheld Imaging (SPY-PHI) System is the same or similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. The clinical data from the FILM-B study demonstrate the performance of the SPY-PHI System when utilized with SPY AGENT GREEN for fluorescence imaging of lymph nodes and delineation of lymphatic vessels in the breast during lymphatic mapping. Risk management activities demonstrated that there are no new risks associated with the expanded indications for use. The combination of these data demonstrate the subject device is the same or similar, with respect to safety and effectiveness, to the legally marketed predicate device.