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

January 23, 2019

Re: K182907
Trade/Device Name: SPY Elite Intraoperative Perfusion Assessment System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: October 16, 2018
Received: October 17, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.01.23 14:19:58 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182907

Device Name
SPY Elite System

Indications for Use *(Describe)*

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.

Examples of its use for near-infrared fluorescence imaging before, during and after various procedures include, but are not limited to, coronary bypass surgery, organ transplant procedures, plastic, reconstructive surgery and micro-surgery (including plastic reconstructive surgery utilizing autologous flaps), renal cancer surgeries, vascular surgeries (such as wound, amputation and coronary vessels), myocardial perfusion in cardiac and cardiovascular surgeries, GI surgeries and parathyroid perfusion during endocrine surgery.

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 Elite Intraoperative Perfusion Assessment System (SPY Elite System)

Device Model Number: LC3000, SP3000

Common Name: Angiographic X-Ray System

Classification: 21 CFR § 892.1600

Classification Name: Angiographic X-Ray System

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
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Date 510(k) Summary Prepared: October 12, 2018

Predicate Device(s): SPY System (K100371, K073088, K073130, and K071619) (Novadaq Technologies Inc.)

Device Description

The SPY Elite System is an angiographic fluorescence imaging system which is used for near-infrared fluorescence imaging during open surgery, with indocyanine green (ICG) as the imaging agent. The SPY Elite System allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels, micro-vessels, tissue and organ perfusion in real-time during various surgical procedures.

The SPY Elite System is comprised of an Imaging Console, CINEVAQ software and DICOM Send software. SPY Elite is intended to be used in conjunction with the SPY Elite Pack/Kit which contains ICG, sterile Water for Injection, a sterile equipment drape, instructions for use, and a drug product package insert.

To provide NIR fluorescence imaging, SPY Elite is used with the imaging agent, indocyanine green (ICG). Once the patient is injected with ICG imaging agent, recording can begin. The SPY Elite imaging head filters the excitation NIR light and only senses the fluorescence signal. Live images are then displayed on the device's monitors. After imaging is complete, the user can review the recorded videos with false color overlays, examine reports and raw data, or print/export still images and reports.

Proposed Indications for Use of the SPY Elite System

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.

Examples of its use for near-infrared fluorescence imaging before, during and after various procedures include, but are not limited to, coronary bypass surgery, organ transplant procedures, plastic, reconstructive surgery and micro-surgery (including plastic reconstructive surgery utilizing autologous flaps), renal cancer surgeries, vascular surgeries (such as wound, amputation and coronary vessels), myocardial perfusion in cardiac and cardiovascular surgeries, GI surgeries and parathyroid perfusion during endocrine surgery.

Comparison and Summary of the Indications for Use of the SPY Elite System and the Predicate Devices

The main differences in the indications for use between the SPY Elite device proposed in this 510(k)-premarket notification and the predicate device are the cross-label indications for use with SPY AGENT™ GREEN drug product, the compilation of the individual 510(k)-cleared indications for use (of the predicate devices) into one comprehensive 510(k), and expansion of the existing indications for use to include pediatrics, one (1) month of age and older.

Summary of Technological Characteristics of the SPY Elite System and Predicate Device

Based on the technological characteristics, principle of operation and fundamental scientific premise, the SPY Elite System (LC3000; SP3000) has been demonstrated to be substantially equivalent to the predicate device, the SPY System (K100371, K073088, K073130, and K071619). The device presented in this premarket notification is an updated version of the predicate device – the SPY System which is FDA 510(k) cleared in K100371, K073088, K073130, and K071619. SPY Elite contains updated system control, processing and image acquisition software, in comparison to the older predicate SPY devices which contain an older type of signal processing software. The CINEVAQ software contained in SPY Elite (applicant device) is the system control software which provides the primary interface for the database, image sequence acquisition, data processing, and review functionality controls on the SPY Elite device.

The proposed device (SPY Elite System) and predicate device (SPY System) are identical in terms of the technology and mode of imaging to provide real-time NIR fluorescence imaging during open surgical procedures. Both the subject and predicate devices utilize the same mode of imaging – near infrared fluorescence imaging, with ICG as the imaging agent, used in the hospital operating room. The proposed and predicate devices have the same integral components – an imaging console, a radiation source, a detector (CCD camera) and signal processing software.

The proposed SPY Elite System is substantially equivalent to the 510(k)-cleared SPY System (K100371, K073088, K073130, and K071619) in terms of its technological characteristics and mode of imaging.

Non-Clinical Performance Testing of the SPY Elite System

The SPY Elite System was designed and developed by Novadaq Technologies in accordance with the applicable requirements and standards to establish performance and safety of the device. Device safety and performance were verified by tests conducted by Novadaq and accredited third party laboratories.

The SPY Elite System was tested in accordance with IEC 60601-1:2012 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*. IEC 60601-1-2:2007 *Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests* conformance testing was also conducted on the SPY Elite System and test results showed that SPY Elite conforms to the applicable requirements. Conformance of SPY Elite with IEC 60825:2007 *Safety of laser products – Part 1: Equipment classification and requirements* was assessed by Underwriters Laboratories Inc. (UL) and showed that SPY Elite is a Class 3R laser device with internal maximum Class 4 laser radiation.

Safety and effectiveness of SPY Elite for visualization of blood flow and tissue perfusion, was assessed in a series of clinical literature evaluations to support the revisions 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.

Clinical Summary for Use in Pediatric Patients

Clinical publications support the safe and effective use of the subject device, in combination with ICG imaging agent, in pediatric patients (1 month to 21 years of age) for perfusion assessments during various surgical procedures.

Efficacy data obtained from published literature showed successful visualization in majority of the studies. Analysis of ICG doses administered to a number of pediatric subpopulations showed that the effective doses used in angiographic applications ranged from 1.25 – 10.0 mg ICG, with the majority of doses being in the range of 1.25 mg to 5.0 mg, 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.

The clinical literature data demonstrates that fluorescence imaging with SPY devices in the angiographic indications of cardiovascular/vascular and plastic, micro-, and reconstructive surgical applications in infant, children and adolescent patients, aged 1 month to 21 years, were effective in visualization of blood flow and tissue perfusion.

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, based on a limited number of pediatrics patients, 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.

Comparison of Device Characteristics of the Subject and Predicate Devices

Company/ 510(k) Holder	**Novadaq Technologies ULC. (Stryker)**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**
Product Brand Name	**SPY Elite System (SUBJECT DEVICE)**	**SPY Intra-Operative Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**
Model	LC3000, SP3000	SP2001	SP2001	SP2001	SP2000
510(k)	Current Submission	K100371	K073088	K073130	K071619
Common Name	Angiographic X-ray System	Angiographic X-ray System	Angiographic X-ray System	Angiographic X-ray System	Angiographic X-ray System
Product Code	IZI	IZI	IZI	IZI	IZI
Regulation Number	21 CFR § 892.1600	21 CFR § 892.1600	21 CFR § 892.1600	21 CFR § 892.1600	21 CFR § 892.1600
Class	II	II	II	II	II
Decision date	Current Submission	02/04/2011	01/10/2008	01/10/2008	11/09/2007
Device Classification Name	System, X-Ray, Angiographic	System, X-Ray, Angiographic	System, X-Ray, Angiographic	System, X-Ray, Angiographic	System, X-Ray, Angiographic
Intended Use	Intraoperative fluorescence angiography; fluorescence imaging of blood flow and tissue perfusion	Intraoperative fluorescence angiography; fluorescence imaging of blood flow and tissue perfusion	Intraoperative fluorescence angiography; fluorescence imaging of blood flow and tissue perfusion	Intraoperative fluorescence angiography; fluorescence imaging of blood flow and tissue perfusion	Intraoperative fluorescence angiography; fluorescence imaging of blood flow and tissue perfusion
Indications for Use	See **NOTE 1** below	The SPY System is intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during gastrointestinal surgical procedures.	The SPY Fluorescent Imaging 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	The SPY Fluorescent Imaging System is intended to intra-operatively enable surgeons to visually asses blood flow and related tissue perfusion during organ transplant procedures.	The SPY Fluorescent Imaging System is intended to provide fluorescent images for the visual assessment of blood flow in vessels and related tissue perfusion during cardiovascular surgical procedures.

Company/ 510(k) Holder	**Novadaq Technologies ULC. (Stryker)**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**
Product Brand Name	**SPY Elite System (SUBJECT DEVICE)**	**SPY Intra-Operative Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**
			perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.		
Device Description Summary	Fluorescence imaging system which allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels and micro-vessels, tissue and organ perfusion in real time while performing a variety of surgical procedures.	Fluorescence imaging system which allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels and micro-vessels, tissue and organ perfusion in real time while performing a variety of surgical procedures.	Fluorescence imaging system which allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels and micro-vessels, tissue and organ perfusion in real time while performing a variety of surgical procedures.	Fluorescence imaging system which allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels and micro-vessels, tissue and organ perfusion in real time while performing a variety of surgical procedures.	Fluorescence imaging system which allows surgeons to capture, review, print, and archive high-quality fluorescence images of blood flow in vessels and micro-vessels, tissue and organ perfusion in real time while performing a variety of surgical procedures.
Principle of Operation	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	Same as subject device	Same as subject device	Same as subject device	Same as subject device

Company/ 510(k) Holder	**Novadaq Technologies ULC. (Stryker)**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**
Product Brand Name	**SPY Elite System (SUBJECT DEVICE)**	**SPY Intra-Operative Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**
	causes the ICG to fluoresce. The fluorescence image signal is processed and simultaneously recorded in computer memory and displayed on the video monitors in real time.				
Environment of Use	Hospital	Hospital	Hospital	Hospital	Hospital
System Components	SPY Elite contains a radiation source, a detector (CCD camera), and signal processing software. The major components of SPY Elite are: • Imaging Console • CINEVAQ Software (1x) – Analysis and Comparison Dashboard • CINEVAQ Software (2x) – Analysis Dashboard and Case Management for vascular imaging modality • DICOM Send Software	SPY contains a radiation source, a detector (CCD camera), and signal processing software. The major components of SPY are: • Imaging Console • HELIOS Software	SPY contains a radiation source, a detector (CCD camera), and signal processing software. The major components of SPY are: • Imaging Console • HELIOS Software	SPY contains a radiation source, a detector (CCD camera), and signal processing software. The major components of SPY are: • Imaging Console • HELIOS Software	SPY contains a radiation source, a detector (CCD camera), and signal processing software. The major components of SPY are: • Imaging Console • DaqPac software
Safety Standards	IEC 60601-1 IEC 60601-1-2	Same as subject device	Same as subject device	Same as subject device	Same as subject device

Company/ 510(k) Holder	**Novadaq Technologies ULC. (Stryker)**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**	**Novadaq Technologies Inc.**
Product Brand Name	**SPY Elite System (SUBJECT DEVICE)**	**SPY Intra-Operative Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**	**SPY Fluorescent Imaging System (PREDICATE DEVICE)**
	IEC 60825-1				
Patient Population	Adult patients and pediatric patients (1 month of age and older)	Adult patients	Adult patients	Adult patients	Adult patients
Contrast Agent	ICG, namely SPY AGENT™ GREEN (Indocyanine green for injection, USP)	ICG	ICG	ICG	ICG
Mode of Imaging	NIR fluorescence imaging	NIR fluorescence imaging	NIR fluorescence imaging	NIR fluorescence imaging	NIR fluorescence imaging

NOTE 1: 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.

Examples of its use for near-infrared fluorescence imaging before, during and after various procedures include, but are not limited to, coronary bypass surgery, organ transplant procedures, plastic, reconstructive surgery and micro-surgery (including plastic reconstructive surgery utilizing autologous flaps), renal cancer surgeries, vascular surgeries (such as wound, amputation and coronary vessels), myocardial perfusion in cardiac and cardiovascular surgeries, GI surgeries and parathyroid perfusion during endocrine surgery.

Conclusions

It has been demonstrated in this Traditional 510(k) premarket notification that the SPY Elite System with the proposed cross-label indications for use is substantially equivalent to the predicate device (SPY System) in terms of safety, effectiveness and performance. This determination is based on the proposed and predicate devices having the same technological characteristics, principle of operation, intended use and environment of use. The proposed cross-label indications for use of the SPY Elite System outlined in this summary raise no issues related to its safety and effectiveness.