Section 5 - 510(k) Summary K190729

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.92.

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)
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Predicate Device:

Device Trade Name:	SPY PHI Open Field Handheld Fluorescence Imaging System
510(k) Reference:	K162885
Submitter Name:	Novadaq Technologies Inc.
Device Common Name:	Fluorescence Angiographic System
Product Code/Regulation:	OWN/ 21 CFR § 892.1600
Classification:	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 in tissue and free flaps used during plastic, micro-, reconstructive, and gastrointestinal 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 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.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device	Predicate Device
	SPY-PHI System	SPY PHI Open Field Handheld Fluorescence Imaging System
510(k) Holder/ Manufacturer	Novadaq Technologies ULC. (now a part of Stryker)	Novadaq Technologies Inc.
Submission Reference	Current Submission	K162885
Combination Product	Yes	Yes
Product Code	OWN	OWN
Regulation	21 CFR 876.1500	21 CFR 876.1500
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
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 in capturing and viewing fluorescence images for the visual assessment of blood flow as an adjunctive method for the evaluation of	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

Feature	Subject Device	Predicate Device
	SPY-PHI System	**SPY PHI Open Field Handheld Fluorescence Imaging System**
	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.	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.
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.
Major components	SPY-PHI imager (with integrated light guide cable) and VPI (Video Processor/ Illuminator)	SPY-PHI imager, light guide cable, VPI (Video Processor/ Illuminator)
Illumination/imaging modes	White light and NIR fluorescence	White light and NIR fluorescence
Image sensor type	Color CMOS	Color CMOS
Fluorescence excitation source	NIR laser	NIR laser
Contrast imaging agent	SPY AGENT™ GREEN (Indocyanine green for injection, USP)	Indocyanine green (ICG)

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.

Additionally, bench testing was performed to demonstrate compatibility of the SPY-PHI System with Stryker ICG - SPY AGENT™ GREEN (Indocyanine green for injection, USP).

Conclusion & Summary of Substantial Equivalence

Based on the information presented in this Special 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 device, the SPY PHI Open Field Handheld Fluorescence Imaging System (FDA 510(k)-cleared in K162885).

Any minor technological or design differences between the SPY-PHI System and its predicate do not raise any questions related to safety or effectiveness. The proposed change to the labeling, proposing use of the SPY-PHI System with Stryker's brand of ICG - SPY AGENT™ GREEN (Indocyanine green for injection, USP), does not raise any issues related to safety or effectiveness for this device-drug combination product.