



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

September 22, 2025

Diagnostic Green GMBH  
% Moj Eram  
RA/QA Sr. Consultant  
Jeff Yuen and Associates  
1121 Military Cutoff Rd  
C 376  
Wilmington, North Carolina 28405

Re: K243645  
Trade/Device Name: IC-Flow™ Imaging System 2.0  
Regulation Number: 21 CFR 892.1600  
Regulation Name: Angiographic X-Ray System  
Regulatory Class: Class II  
Product Code: IZI  
Dated: September 18, 2025  
Received: September 18, 2025

Dear Moj Eram:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**TANISHA**  
**L. HITHE -S**

Digitally signed by  
TANISHA L. HITHE -S  
Date: 2025.09.22  
18:11:01 -04'00'

Tanisha Hithe  
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

## Indications for Use

510(k) Number (if known)  
K243645

Device Name  
IC-Flow™ Imaging System 2.0

### Indications for Use (Describe)

IC-Flow™ Imaging System 2.0, used in conjunction with Indocyanine Green (ICG), is indicated for fluorescence imaging of blood flow, tissue perfusion, and the lymphatic system in both adult and pediatric patients one month of age and older. Upon intravenous administration of ICG, the IC-Flow™ Imaging System 2.0 is used for fluorescence angiography before and after vascular, and plastic, micro-, and reconstructive procedures. Additionally, upon subcutaneous administration, the system is used for fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels.

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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## **510(k) Summary** **#K243645**

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

### **Submitter and Regulatory Information – (21 CFR 807.92(a)(1))**

<b>Submitter Information</b>	
Name	Diagnostic Green GmbH
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Contact Name	Ann M Maloney
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Date Summary Prepared	12 September 2025
<b>Primary Regulatory Contact</b>	
Name	Moj Eram, PhD
Title	Regulatory Affairs Consultant Jeff Yeun and Associates
Telephone Number	801-230-8611 (Mobile)
Email	<a href="mailto:Moj_eram@jeffyeun.com">Moj_eram@jeffyeun.com</a>

### **Name of the Device – (21 CFR 807(a)(2))**

Trade Name	IC-Flow™ Imaging System 2.0
Classification Name	Angiographic X-Ray System
Regulatory Class	Class II
Product Code	IZI
Regulation Number	21 CFR 892.1600
Regulation Medical Specialty	Radiology
Review Panel	General & Plastic Surgery

### **Predicate Information – (21 CFR 807(a)(3))**

<b>Table 10-3A: Predicate Device Regulatory Information</b>		
<b>Regulatory Information</b>	<b>Predicate Device 1 SPY-PHI (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
<b>K Number</b>	K230727	K133719
<b>Device Name</b>	SPY Portable Handheld Imaging (SPY-PHI) System	Pde-neo
<b>Manufacturer/ Applicant</b>	Novadaq Technologies ULC	HAMAMATSU PHOTONICS, K.K.
<b>Date of Clearance</b>	06/05/2023	03/27/2014
<b>Device Classification Name</b>	Angiographic X-ray System	Angiographic X-ray System
<b>Device Classification</b>	Class II	Class II
<b>Product Code</b>	IZI	IZI Subsequent: OWN
<b>Regulation Number</b>	21 CFR 892.1600	21 CFR 892.1600
<b>Regulation Definition</b>	Angiographic X-ray System	Angiographic X-ray System
<b>Regulatory Medical Specialty</b>	Radiology	Radiology
<b>Review Panel</b>	General & Plastic Surgery	Radiology

### Device Description

The IC-Flow™ Imaging System 2.0 is a real time near-infrared (NIR) fluorescence imaging system which facilitates visualization of the distribution and intensity of the Indocyanine Green (ICG) fluorescent imaging agent during medical procedures.

The IC-Flow™ Imaging System 2.0 consists of a Controller with further connections to LAN and HDMI and a handheld Camera. The IC-Flow™ Imaging System 2.0 has a medical, near-infrared (NIR) Camera which emits a light to excite the ICG molecules and view ICG emitted fluorescence. The captured fluorescent image data is displayed on the Controller and/or connected monitor.

Images and videos are recorded using buttons located on the Camera and icons on the Controller. The NIR light source illumination (excitation light) and Camera sensitivity can also be adjusted using controls on either the Camera or Controller. Images are stored in the Controller but can easily be transferred to a USB memory device, Cloud Drive or an external mass storage device.

When ICG is injected consistent with its indications for use, it binds to plasma proteins and exhibits fluorescence when illuminated with near infrared (NIR) light. The excitation light source of IC-Flow™ imaging System 2.0 consists of a high-power LED.

**Intended Use**

IC-Flow™ Imaging System 2.0, used in conjunction with Indocyanine Green (ICG), is indicated for fluorescence imaging of blood flow, tissue perfusion, and the lymphatic system in both adult and pediatric patients one month of age and older. Upon intravenous administration of ICG, the IC-Flow™ Imaging System 2.0 is used for fluorescence angiography before and after vascular, and plastic, micro-, and reconstructive procedures.

Additionally, upon subcutaneous administration, the system is used for fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels.

**Comparison of Technological Characteristics with the Predicate Devices**

A comparison of the subject device, IC-Flow™ Imaging System 2.0 and predicate devices, SPY Portable Handheld Imaging (SPY-PHI) System (K230727) & Pde-neo (K133719), is based on the following same technologies:

- Similar Intended Use / Indications for Use (IC-Flow 2.0 is not intended for use during surgery)
- Same requirement for ICG as imaging agent
- Similar operating principle with camera positioned toward observed area
- Using LED as light source
- Similar optical imaging specifications
- Same intended user by Physicians and healthcare professional (IC-Flow 2.0 is not intended for use during surgery)
- Same operating environment when not used in the operating room (IC-Flow 2.0 is not intended for use during surgery)

In addition to the same and similarities stated above, the differences in the technological characteristics between the subject device, IC-Flow™ Imaging System 2.0 and Predicate devices, SPY Portable Handheld Imaging (SPY-PHI) System (K230727) & Pde-neo (K133719) do not pose questions on safety and/or performance of the subject device and as has shown with safety and performance testing.

<b>Table 10-3B: Subject and Predicate Devices Comparison</b>			
	<b>Subject Device IC-Flow™ Imaging System 2.0</b>	<b>Predicate Device 1 SPY Portable Handheld Imaging (SPY-PHI) System (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
<b>510(k) Number</b>	Current Submission	K230727	K133719
<b>Sponsor / Owner</b>	Diagnostic Green GmbH	Novadaq Technologies ULC	HAMAMATSU PHOTONICS, K.K.

<b>Table 10-3B: Subject and Predicate Devices Comparison</b>			
	<b>Subject Device IC-Flow™ Imaging System 2.0</b>	<b>Predicate Device 1 SPY Portable Handheld Imaging (SPY-PHI) System (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
<b>Regulation Number</b>	21 CFR 892.1600	21 CFR 892.1600	21 CFR 892.1600
<b>Product Code</b>	IZI	IZI	IZI
<b>Intended Use</b>	Visible white light and near-infrared illumination during vascular and lymphatic assessments and before and after surgical procedures.	Visible white light and near-infrared illumination during open-field surgical procedures.	The pde-neo 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 organ transplant surgeries.
<b>Indications for Use</b>	<p>IC-Flow™ Imaging System 2.0, used in conjunction with Indocyanine Green (ICG), is indicated for fluorescence imaging of blood flow, tissue perfusion, and the lymphatic system in both adult and pediatric patients one month of age and older. Upon intravenous administration of ICG, the IC-Flow™ Imaging System 2.0 is used for fluorescence angiography before and after vascular, and plastic, micro-, and reconstructive procedures.</p> <p>Additionally, upon Subcutaneous administration, the system is used for fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels.</p>	<p>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.</p>	<p>The pde-neo 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 organ transplant surgeries.</p>

<b>Table 10-3B: Subject and Predicate Devices Comparison</b>			
	<b>Subject Device IC-Flow™ Imaging System 2.0</b>	<b>Predicate Device 1 SPY Portable Handheld Imaging (SPY-PHI) System (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
		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.	
<b>Device Description</b>	<p>The IC-Flow™ Imaging System 2.0 is a real time near-infrared (NIR) fluorescence imaging system which facilitates visualization of the distribution and intensity of the Indocyanine Green (ICG) fluorescent imaging agent during medical procedures.</p> <p>The IC-Flow™ imaging System 2.0 consists of a Controller with further connections to LAN and HDMI and a handheld Camera. The IC-Flow™ imaging System 2.0 has a medical, near-infrared (NIR) Camera which emits a light to excite the ICG molecules and view ICG emitted fluorescence. The captured fluorescent image data is displayed on the Controller and/or connected monitor.</p> <p>Images and videos are recorded using buttons located on the Camera and icons on the Controller. The NIR light source illumination (excitation light) and Camera sensitivity can also be adjusted using controls on</p>	<p>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.</p>	<p>The pde-neo is an imaging system used in capturing and viewing</p> <p>fluorescent images for the visual assessment of blood flow, as an</p> <p>adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive, and organ transplant surgeries. The pde-neo is intended for intraoperative visual assessment of blood vessels and related tissue perfusion by enabling surgeons to observe fluorescent images of blood vessels and related tissue perfusion. Indocyanine green (ICG) is injected intravenously into patients. Infrared light-emitting diodes (LEDs) are used to excite the fluorescence of ICG and illuminate the regions of a patient's anatomy to be observed. A charge</p>

<b>Table 10-3B: Subject and Predicate Devices Comparison</b>			
	<b>Subject Device IC-Flow™ Imaging System 2.0</b>	<b>Predicate Device 1 SPY Portable Handheld Imaging (SPY-PHI) System (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
	<p>either the Camera or Controller. Images are stored in the Controller but can easily be transferred to a USB memory device, Cloud Drive or an external mass storage device.</p> <p>When ICG is injected consistent with its indications for use, it binds to plasma proteins and exhibits fluorescence when illuminated with near infrared (NIR) light. The excitation light source of IC-Flow™ imaging System 2.0 consists of a high-power LED.</p>		<p>coupled device (CCD) camera captures the fluorescent image that is used to assess the blood vessels and related tissue perfusion.</p> <p>The pde-neo consists of the following components: Camera Unit, Controller, and Remote Controller. The Camera Unit contains a CCD camera and LED light sources and is used either by hand or attaching it to a mechanical arm. The Controller receives the video signal of the fluorescent image from the Camera Unit and outputs the processed fluorescent image to the external video monitor and recorder.</p> <p>Adjustments of the fluorescent image are possible either by the Camera Unit or the Remote Controller.</p>
<b>System Components</b>	<ul style="list-style-type: none"> <li>• Camera</li> <li>• Camera Cable</li> <li>• Controller</li> <li>• Power Unit</li> <li>• Stand + 4 screws</li> <li>• HDMI Cables</li> </ul>	<ul style="list-style-type: none"> <li>• SPY-PHI Imager</li> <li>• Video Processor/ Illuminator</li> <li>• SPY-QP Fluorescence Assessment Software</li> </ul>	<ul style="list-style-type: none"> <li>• Camera Unit</li> <li>• Controller</li> <li>• Remote Controller</li> </ul>
<b>Environment for Use</b>	Hospitals and Clinics	Operating room	Operating room
<b>Intended User</b>	Physicians, trained healthcare professionals	Physician, or under supervision of physician	Surgeon or assistance
<b>Principle of Operation</b>	IC-Flow™ Imaging System 2.0 is near infrared imaging system. The handset camera is positioned over the patient such that the NIR excitation light is emitted and illuminates the area	Full color visible light and NIR fluorescence video imaging. The imaging head is positioned over the patient such that the NIR excitation light is emitted and	The pde-neo II is a medical infrared camera designed to observe the fluorescent images from indocyanine green (ICG) in the patient's body. It is equipped with

<b>Table 10-3B: Subject and Predicate Devices Comparison</b>			
	<b>Subject Device IC-Flow™ Imaging System 2.0</b>	<b>Predicate Device 1 SPY Portable Handheld Imaging (SPY-PHI) System (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
	<p>of interest. When the patient is injected with ICG, the ICG binds to the plasma in the blood and travels through the blood to the area of interest. The camera captures the fluorescent image, the controller receives the video signal and displays the video image on the integrated touchscreen and if available on a connected monitor.</p> <p>Pictures and videos can be recorded and stored on the memory of the controller and can be transferred to a Cloud Drive, USB stick or an external memory device.</p>	<p>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.</p>	<p>Light Emitting Diodes (LEDs) used to excite the fluorescence from ICG.</p> <p>The camera is positioned toward the observed area such that the excitation light is irradiated from the camera window to the observed area. When the patient is injected with ICG, the ICG binds to plasma in the blood and travels to the area of interest through the bloodstream. The camera captures the fluorescent image or a color image under white light illumination. External video monitor and recorder are connected to the controller, receiving the video signal and displaying the video image.</p>
<b>Imaging Mode</b>	Fluorescence mode	White Light  Near-Infrared: <ul style="list-style-type: none"> <li>- Overlay Mode 1</li> <li>- SPY Mode (Contrast) 1</li> <li>- SPY Color Segmented Fluorescence (CSF)</li> </ul>	LED light
<b>Light Source</b>	LED	LED and NIR laser	LED
<b>Optical Imaging Specification</b>	<p>Continuous wave lamp (CW) The camera has a resolution of 1920x1200 pixels.</p> <p>Working distance is 170-200 mm Image section 75x100 mm. Camera lens depth 47 mm</p>	<p><u>Dynamic Range</u> 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</p>	Unknown

<b>Table 10-3B: Subject and Predicate Devices Comparison</b>			
	<b>Subject Device IC-Flow™ Imaging System 2.0</b>	<b>Predicate Device 1 SPY Portable Handheld Imaging (SPY-PHI) System (Primary)</b>	<b>Predicate Device 2 Pde-neo</b>
		<p>maximum clinically relevant concentration shall be at least twice that at low concentrations.</p> <p><u>Localization</u>            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.</p>	
<b>Imager</b>	Image Sensor: Complementary Metal Oxide Semiconductor (CMOS) Image Sensor	Image Sensor: Complementary Metal Oxide Semiconductor (CMOS) Image Sensor	Image Sensor: Charge Coupled Device (CCD) Image Sensor
<b>Video Processor / Illuminator</b>	LED, Near Infrared 1920 x1200 pixels	<ul style="list-style-type: none"> <li>• Light Source: RGB LEDs</li> <li>• Laser: Infrared Laser</li> <li>• Laser Safety Class: Class 3R</li> <li>• Image Processing Video Output: Digital</li> <li>• Resolution 2180p (1920 x 1080)</li> </ul> Frame Rate: 60 Hz	LED
<b>Safety Standards</b>	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60825-1	EC 60601-1 IEC 60601-1-2 IEC 60825-1
<b>Single Use / Reusable</b>	Reusable	Reusable	Reusable
<b>Patient Contacting</b>	No direct or indirect patient contact	No direct or indirect patient contact	No direct patient contact
<b>Prescription or Over the Counter</b>	Prescription Only	Prescription Only	Prescription Only
<b>Imaging Agent</b>	ICG (Indocyanine Green for Injection)	SPY AGENT™ GREEN (Indocyanine green for injection, USP)	ICG (Indocyanine Green for injection) from PDE/pde-neo II Kit

**Summary of Safety and Performance Testing**

**Table 10-3C** provides a summary of the testing performed to address the risks associated with the subject device, IC-Flow™ Imaging System 2.0. All tests were conducted based on the predetermined acceptance criteria and passed the required testing.

<b>Table 10-3C: IC-Flow™ Imaging System 2.0, Safety and Performance Testing Summary</b>		
<b>Test</b>	<b>Standards</b>	<b>Test Description</b>
Software Lifecycle	IEC 62304	Software Development and V&V
Electrical Safety	IEC 60601-1	Safety Testing
Electromagnetic Compatibility	IEC 60601-1-2	EMC Testing
Basic Safety and Essential Performance	IEC 60601-1-6	Usability Testing
EMC Testing / Radio Equipment	EN 301 489-1 v2.2.1 EN 301 893 V2.1.1 EN 301 328 V2.2.2	EMC / Radio Equipment
Photobiological Safety of Lamps and Lamp System	IEC 62471	Lamp Safety
Cleaning and Disinfection	Internal protocol	Manual Cleaning and Disinfection
Service Life	IEC 60601-1	EMC
Packaging	Internal protocol	Drop, Vibration, Compression
Performance Testing / Usability	IEC 62366-1 & Internal Protocol	Usability Testing & Device Performance
Performance Testing (Bench)	Internal Protocol	Performance Testing on Attributes
Performance Testing (In vivo)	Clinical Demonstration	ICG Imaging Video and Image Capture
Performance Testing (Animal)	N/A - No animal studies were required as appropriate verification of the subject devices was achieved based on the comparison to the predicate devices and from the results of the bench testing and engineering analysis.	
Performance Testing (Clinical)	N/A – No clinical studies were required as appropriate verification of the subject devices was achieved based on the comparison to the predicate devices and from the results of the bench testing and engineering analysis.	
Sterilization	N/A – IC-Flow™ Imaging System 2.0 is not offered sterilized and does not require sterilization.	
Biocompatibility	N/A – IC-Flow™ Imaging System 2.0 is not patient contacting (direct or indirect).	

## Conclusion

The IC-Flow™ Imaging System 2.0 has the same or similar design, intended use, indications for use, principle of operation, and safety features as the predicate devices, the SPY Portable Handheld Imaging (SPY-PHI) System (K230727) and the pde-neo (K133719). The subject device also demonstrates

substantially equivalent technological characteristics and has been shown to be as safe and effective as the identified predicate devices.

Any technological differences between the IC-Flow™ Imaging System 2.0 and its predicate devices do not raise new or different questions of safety or effectiveness. Comprehensive risk management activities conducted in accordance with ISO 14971 confirm that no new risks are introduced by the subject device. Based on the intended use, technological characteristics, and results from safety and performance testing, the IC-Flow™ Imaging System 2.0 meets the necessary requirements for its intended application. Therefore, the subject device is considered substantially equivalent to the SPY-PHI System (K230727) and the pde-neo (K133719).