



November 21, 2018

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

Re: K182606

Trade/Device Name: PINPOINT Endoscopic Fluorescence Imaging System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: GCJ, IZI  
Dated: September 20, 2018  
Received: September 21, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**David Krause -S**

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

## Indications for Use

510(k) Number (if known)

K182606

Device Name

PINPOINT Endoscopic Fluorescence Imaging System

Indications for Use (Describe)

Upon intravenous administration of TRADENAME (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with TRADENAME 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 TRADENAME (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.

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:** PINPOINT Endoscopic Fluorescence Imaging System

**Device Model Number:** PC9000

**Common Name:** Endoscope Video Imaging System

**Classification:** 21 CFR § 876.1500

**Classification Name:** Laparoscope, General & Plastic Surgery; Angiographic X-ray System

**Product Code:** GCJ

**Subsequent 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  
Regulatory Affairs Manager  
Tel: (604) 422-7516  
Fax: (604) 232-9841

**Date 510(k) Summary Prepared:** November 15, 2018

**Predicate Device:** PINPOINT Endoscopic Fluorescence Imaging System (K150956 and K161792)  
(Novadaq Technologies Inc.)

### Device Description:

The PINPOINT Endoscopic Fluorescence Imaging System (PINPOINT, PINPOINT System) is comprised of an endoscopic video processor/ illuminator (VPI) which is capable of providing visible and near-infrared illumination to a surgical laparoscope, surgical laparoscopes optimized for visible (VIS) and near-infrared (NIR) illumination and imaging, a camera head that is also optimized for visible and near-infrared imaging, and a flexible light guide cable. The following laparoscope models are included as part of the PINPOINT System: SC9104, SC9134, SC9144, SC9504, SC9534, SC9544, SC9101 and SC9131. These are the major components of the PINPOINT System.

During surgical procedures, PINPOINT may be operated to provide visualization similar to that provided by conventional imaging systems used in surgical endoscopy. The area of interest is illuminated with visible light from the illuminator and the resulting reflected light is imaged by the camera and displayed on the video monitor. When used with the VIS-only laparoscopes, the System is only capable of the conventional mode of visualization described herein.

To provide NIR fluorescence imaging, PINPOINT is used with the imaging agent, indocyanine green (ICG). The patient is injected with ICG imaging agent. The ICG fluoresces when illuminated through the laparoscope with NIR excitation light from the VPI, and the fluorescence response is then imaged with the camera, processed and displayed on an HD video monitor.

When used with a VIS/NIR laparoscope, PINPOINT can operate to provide illumination and imaging of both visible light and ICG fluorescence images simultaneously.

### **Proposed Indications for Use of the PINPOINT System:**

Upon intravenous administration of TRADENAME (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with TRADENAME 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 TRADENAME (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.

### **Examples of the PINPOINT System's Use during Various Procedures**

Examples of the PINPOINT System's use for near-infrared imaging during various minimally invasive procedures include, but are not limited to, renal cancer perfusion, GI tract perfusion during surgery of the colon, stomach or esophagus and parathyroid perfusion during endocrine surgery. An example of the PINPOINT System's use in lymphatic visualization includes fluorescence imaging of lymph nodes and delineation of lymphatic vessels in the cervix and uterus in patients with solid tumors during lymphatic mapping.

### **Summary of Technological Characteristics of the PINPOINT System and Predicate Device**

Based on the technological characteristics, fundamental scientific premise, and intended use, the PINPOINT Endoscopic Fluorescence Imaging System (PC9000) has been demonstrated to be

substantially equivalent to the predicate device, the PINPOINT Endoscopic Fluorescence Imaging System (K150956 and K161792). The device presented in this submission is identical to the predicate device – the PINPOINT System which is FDA 510(k) cleared in K150956 and K161792. The only difference between the device presented in this 510(k) submission and the predicate device are the expanded indications for use for imaging and visualization of the lymphatic system. The PINPOINT Endoscopic Fluorescence Imaging System is a combination product, with the PINPOINT System being the device component and the ICG imaging agent (TRADENAME, indocyanine green for injection, USP) being the drug component.

The proposed device (PINPOINT System) and predicate device (PINPOINT System) are identical in terms of the technology and mode of imaging to provide real-time endoscopic visible and NIR fluorescence imaging during minimally invasive surgical procedures. The system utilizes the same mode of imaging – visible and near infrared fluorescence imaging, with ICG as the imaging agent, used in the hospital operating room. The proposed and predicate device have the same integral components – a light source console and a light cable for outputting light, a camera control unit for processing NIR and VIS light images, a coupler attached to the laparoscope and a camera head, and laparoscopes for VIS and NIR light illumination and imaging. The proposed PINPOINT System is substantially equivalent to the existing PINPOINT System (K150956 and K161792) in terms of its technological characteristics, mode of imaging, and intended use; the only difference are the expanded indications for use with TRADENAME (indocyanine green for injection, USP) drug product for lymphatic imaging.

### **Non-Clinical and Clinical Performance Testing of the PINPOINT System**

The PINPOINT System was designed and developed by Novadaq Technologies ULC. (Novadaq, formerly Novadaq Technologies Inc.), 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 PINPOINT 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 PINPOINT System and test results showed that PINPOINT conforms to the applicable requirements. PINPOINT was also tested in accordance with IEC 60601-2-18:2009 *Medical Electrical Equipment – Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment* and has demonstrated conformance to the standard. Conformance of PINPOINT with IEC 60825:2007 *Safety of laser products – Part 1: Equipment classification and requirements* was assessed by Underwriters Laboratories Inc. (UL) and showed that PINPOINT is a Class 3R laser device with internal maximum Class 4 laser radiation.

Safety and performance of PINPOINT for visualization of blood flow and tissue perfusion, and for visualization of the main extrahepatic biliary ducts was assessed in series of clinical literature evaluations to support the revisions to the cleared indications for use.

Data from a Phase III, randomized controlled clinical trial with the PINPOINT System and TRADENAME (indocyanine green for injection, USP) drug product supports the new proposed lymphatic indications for use.

## **Conclusions**

It has been demonstrated in this Traditional 510(k) submission that the PINPOINT System with the proposed expanded indications for use is substantially equivalent to the predicate device (PINPOINT 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, and intended use. The proposed expanded indications for use of the PINPOINT Endoscopic Fluorescence Imaging System outlined in this summary raise no issues related to its safety and effectiveness.