DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 23, 2016

Novadaq Technologies Inc.
Ms. Jen Pendlebury
Director of Regulatory Affairs
8329 Eastlake Drive Unit 101
Burnaby, British Columbia
Canada V5A 4W2

Re: K150956
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: May 13, 2016
Received: May 16, 2016

Dear Ms. Pendlebury:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150956

Device Name
PINPOINT Endoscopic Fluorescence Imaging System (PC9000)

Indications for Use *(Describe)*
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.

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; IZI

Classification: Class II

Manufacturer:
Novadaq Technologies Inc.
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Burnaby, British Columbia
Canada V5A 4W2

Contact Name:
Jen Pendlebury
Director of Regulatory Affairs
Tel: (905) 629-3822 ext. 205
Fax: (905) 249-0656

Date 510(k) Summary Prepared: May 12, 2016

Predicate Devices:
SPY Scope Intra-Operative Imaging System/ PINPOINT (K091515)
(Novadaq Technologies Inc.)

Da Vinci Firefly Imaging System (K141077) (Intuitive Surgical, Inc.)

Stryker Infrared Light Source and SafeLight Cable (K142310) (Stryker Endoscopy)

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: SC9100, SC9101, SC9104, SC9130, SC9131, SC9134 and SC9144. 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:

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.

Summary of Technological Characteristics of the PINPOINT System and Predicate Devices

Based on the technological characteristics and fundamental scientific premise, the PINPOINT System (PC9000) has been determined to be substantially equivalent to the predicate devices, the SPY Intra-Operative Imaging System/PINPOINT (K091515), as well as the da Vinci Firefly Imaging System (K141077) and the Stryker IRF Light Source and SafeLight Cable (K142310). PINPOINT is substantially equivalent to the SPY Scope Intra-Operative Imaging System (SC8000), as both systems use the same technology and mode of imaging to provide real-time endoscopic visible and NIR fluorescence imaging during minimally invasive surgical procedures. PINPOINT is also substantially equivalent to the da Vinci Firefly Imaging System (K141077) and to the Stryker IRF Light Source and SafeLight Cable (K142310). Both systems and PINPOINT utilize very similar technology and rely on the same scientific premise – they are endoscopic video imaging systems which are used for high definition visible light and NIR fluorescence imaging during minimally invasive surgery. All of these systems utilize the same mode of imaging – visible and near infrared fluorescence imaging, with ICG as the imaging agent, used in the hospital operating room. All of these systems 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 a laparoscope for VIS and NIR light illumination and imaging.

Performance Data:

Non-Clinical Performance Testing of the PINPOINT System

The PINPOINT System was designed and developed by Novadaq Technologies Inc. (NOVADAQ), 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.

Animal testing using a porcine model validated the *in vivo* fluorescence imaging capability of the PINPOINT System.

Clinical Performance Data

A clinical evaluation based on a clinical literature search and reported clinical adverse event information from post-market surveillance was considered appropriate to evaluate the performance and safety of the PINPOINT System. It was concluded to objectively verify the continued clinical safety and performance of NOVADAQ'S Fluorescence Imaging devices, including the PINPOINT System.

Data presented in the clinical evaluation report provides evidence to support the safety and performance claims for the PINPOINT System. Additionally, results from a clinical study and case reports utilizing the PINPOINT System and published in the *Journal of Gastrointestinal Surgery* and in *Surgical Innovation* and *Intl J Sur Case Reports*, respectively, together with findings from the most recent literature search are enclosed to support the expanded Indications for Use of PINPOINT (see section 20, Performance Testing - Clinical, for the summary of the relevant clinical literature reports). Findings demonstrated that no new concerns related to the safety and effectiveness of the device have been introduced.

Conclusions

It has been demonstrated in this 510(k) submission that the PINPOINT System, with the expanded Indications for Use, is substantially equivalent to the predicate devices discussed herein and there are no issues related to its safety or effectiveness. The additional performance data and scientific literature from a recent literature search supports the expanded Indications of the device, and further validates the well-established safety profile of NOVADAQ'S imaging systems.