K091515

510(k) Summary

JUL - 9 2009

Date Summary Prepared:	May 14, 2009
Trade Name:	SPY® scope Intra-operative Imaging System
Common Name:	Endoscope Video Imaging System
Classification Name:	Laparoscope, General & Plastic Surgery
Reg. Classification:	21 CFR 876.1500
Classification:	II
Product Code:	GCJ
Manufacturer:	Novadaq Technologies Inc. 2585 Skymark Avenue, Suite 306 Mississauga, Ontario, Canada, L4W 4L5 **Tel:** (905) 629-3822 **Fax:** (905) 629-8779
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Legally Marketed Predicate Devices:

The Novadaq SPY scope Intra-operative Imaging System (SPY scope), Model: SC8000 was compared by product component and found to be equivalent to the following devices and device components. SPY scope has the same fundamental functional characteristics and indications for use of these predicate devices and components.

Imaging Technology

Novadaq SPY Intra-operative Imaging System (K073088)

Leica FL800 (K061871)

Endoscope

Stryker Laparoscope (K910132)

Circon ACMI USA Series Laparoscope (K013165)

Camera and Light Source

Linvatec HD Digital Camera System (K063457)

Circon Metal Halide Light Source (K012265)

Device Description:

The SPY® scope provides real-time high definition (HD) endoscopic video images of visible (VIS) and near infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive surgery. During such a procedure, the SPY scope functions like all conventional VIS light imaging systems used in surgical endoscopy. Visible light from the SPY scope light source illuminates the area of interest through the endoscope and the resulting reflected light is imaged by the SPY scope color HD camera and displayed on an HD video monitor.

The SPY scope device is comprised of the following components:

1. Endoscopes for VIS and NIR illumination and imaging,
2. A 3 CCD (charge coupled device) color video camera head with video coupler and accompanying sterile drape,
3. Light source & video processor unit, and
4. ICG imaging agent.

Proposed Intended Use / Indications for Use:

The SPY scope is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. SPY scope enables surgeons to perform routine visible light endoscopic procedures as well as further visually assess vessels, blood flow and related tissue perfusion with near infra-red imaging during minimally invasive surgery.

Substantial Equivalence:

As noted, the SPY scope is equivalent to several cleared devices and components. The SPY scope has the same fundamental functional characteristics as these predicate devices, as summarized below.

Imaging Technology

The Novadaq SPY Intra-operative Imaging System (K073088)

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 in plastic, micro- and reconstructive surgical procedures.

Leica FL800 (K061871)

The Leica FL800 is a surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area.

Endoscope

Stryker Laparoscope (K910132)

Laparoscopes are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments. This includes, but is not limited to such uses

as gallbladder and appendix removal, hernia repair, gastric bypass, laparoscopic Nissen and examination of the abdominal cavity, appendix, gallbladder and liver.

Circon ACMI USA Series Laparoscope (K013165)

Circon ACMI USA Series Laparoscopes are intended to be used by qualified physicians to provide access, illumination and visualization of body cavities, hollow organs, and canals during endoscopic and laparoscopic surgical procedures. These include, but are not limited to, laparoscopic procedures used in general surgical procedures, cholecystectomy, colon resection or therapeutic thorascopy.

Camera System and Light Source

Linvatec HD Digital Camera System (K063457)

The Linvatec HD Digital Camera System is 3 CCD HD color camera system intended for use in a variety of endoscopic surgical procedures including but not limited to orthopedic, laparoscopic, urologic, sinuscopic, plastic and as an accessory for microscopic surgery.

Circon Video Metal Halide Light Source (K012265)

The Circon Video Metal Halide Light Source is a non-Xenon endoscopic light source to provide optimized light for viewing procedures carried out with flexible and rigid endoscopes. These devices are marketed as reusable.

Rationale for Substantial Equivalence

The basis for substantial equivalence with the Imaging Technology is as follows: the SPY scope essentially uses the same imaging technology as the SPY System used in open surgical procedures. The SPY System currently uses a laser light source to illuminate the area of interest. In order to obtain the images, ICG is injected intravenously through the central or peripheral venous line. While the ICG is passing through the vessels, the absorption of laser light causes excitation of the ICG, followed by the emission of infrared energy. A CCD camera of the SPY System captures the infrared emission, resulting in a fluorescent image of blood flow and related tissue perfusion. The SPY scope works essentially the same way: For ICG fluorescence imaging during endoscopic surgery, the patient is injected intravenously with ICG imaging agent. The ICG fluoresces when illuminated through the endoscope with near NIR excitation light from the SPY scope light source. The fluorescence response is then imaged with the SPY scope CCD camera, processed and displayed on an HD video monitor.

With respect to substantial equivalence with the above mentioned endoscopes (Stryker, and USA Series), the SPY scope endoscope is used during minimally invasive surgical procedures to provide access, illumination, and visualization of body cavities, and hollow organs. Similar to the predicates, the SPY scope endoscope has a diameter of 10 mm, with similar direction of view of 0° and 30°, and autoclavable.

With respect to the camera system, the SPY scope is substantially equivalent to the Linvatec HD digital camera system since they both consist of a camera control unit and a 3 CCD camera head for HD visualization during minimally invasive surgical procedures.

The primary visible light source for the SPY scope is a mercury arc lamp, which is substantially equivalent to the Circon Metal Halide Light Source in visible light output and indication for use.

Testing:

In vitro and non-clinical studies were conducted to support the safe and effective use of the SPY scope device.

In Vitro Testing:

Testing of the SPY scope device includes in-house testing and 3rd party certification of conformance to the following standards[1]:

1. IEC 60601-1; Medical electrical equipment – Part 1: General requirements for safety; 1988, Am1 1991, Am2 1995
2. IEC 60601-1-2; Medical electrical equipment – Part 1-2: General requirements for safety, Collateral standard. Electromagnetic compatibility – Requirements and tests; 2001, Am1 2004
3. IEC 60601-1-4; Medical electrical equipment – Part 1: General requirements for safety, Collateral standard: Programmable electrical medical systems; 2000
4. IEC 60601-2-18; Medical electrical equipment – Part 2: Particular requirements for the safety of endoscopic equipment; 1996, Am1 2000
5. IEC 60825-1; Safety of laser products – Part 1: Equipment classification and requirements; 2007
6. 21 CFR 1040.10 and 21 CFR 1040.11; Performance Standards for Light-Emitting Products (except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007)

In addition, comparisons of SPY scope images were made with previously cleared endoscopes to ensure image quality is at least equivalent to previously cleared and marketed endoscopes.

In Vivo Testing:

The functionality of the SPY scope was validated in imaging studies performed on 6 dogs and 10 pigs. The studies were undertaken at the National Research Council of Canada, Winnipeg, University of Rochester, Rochester, New York, Intuitive Surgical Inc, Sunnyvale, California and St Joseph's Translational Research Institute, Atlanta, Georgia following ethics approval by the appropriate animal care committee. The details of the imaging results varied depending upon the availability of complementary equipment and expertise. Thus, the 6 dogs were imaged in full laparoscopic manner, i.e. with insertion of the laparoscope through a small port and insufflation of the body cavity. Three of the pigs were imaged in laparoscopic/thoracoscopic manner in conjunction with use of a commercially available robotic system. The remaining pigs were imaged following exposure of the relevant anatomy by an open surgical technique, placement of the

[1] The following additional standards were referenced by predicate devices, which do not apply to the SPY scope device:

- ANSI Z136.1 applies to users of laser systems. Relevant requirements are covered by IEC 60825-1.
- ANSI Z136.3 applies to health care facilities using laser products. Relevant requirements are covered by IEC 60825-1.
- IEC 60601-2-22 applies to laser products of Class IIIB or IV only. SPY scope is a Class IIIR laser product and is not subject to this standard.

endoscope through the incision and draping of the surgical incision to create a pseudo-laparoscopic view.

When injected intravascularly, ICG rapidly and extensively binds to plasma proteins and thus is confined to the vascular compartment. The ICG is removed from the blood by the liver with a plasma half life of 3-5 minutes. The ICG is excreted from the liver via the bile without further metabolism, appearing in the bile within 10-15 minutes of administration. Following extra vascular administration, ICG is taken up by the local lymphatics within seconds and in the local lymph nodes within minutes. This ICG will ultimately be delivered to the thoracic duct and gradually enter the venous return to the heart and thus slowly be taken up and eliminated by the hepato-biliary system.
Utilizing the properties of ICG the following anatomical features were successfully imaged and summary of which is included in the Performance Data Section of this Traditional Premarket Notification 510(k) submission:

1. Cardiovascular
    a. Flow through the femoral artery
    b. Flow through the renal artery and vein
    c. Imaging of the native coronary arteries and veins
    d. Imaging of a coronary artery bypass graft, specifically the left internal mammary artery (LIMA) grafted to the left anterior descending (LAD) coronary artery.
2. Organ perfusion
    a. Kidney
    b. Liver
    c. Bowel
3. Biliary anatomy.
4. Lymphatics and associated lymph nodes.

Conclusions:

The above testing demonstrates that the SPY scope device is substantially equivalent in function and indications for use to several devices and components of endoscopic video and NIR imaging systems. In addition, the data presented herein demonstrates that SPY scope device performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL - 9 2009

Re: K091515
Trade/Device Name: SPY® scope Intra-operative Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, IZI
Dated: May 20, 2009
Received: May 22, 2009

Dear Ms. Fontaine:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N.Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 091515

Device Name: SPY® scope Intra-operative Imaging System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neal R. Ogden for mkm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091515