510(k) Summary

K073088

Trade Name: SPY® Fluorescent Imaging System

Device Model Number: SP2001

Common Name: Fluorescent Angiographic System

JAN 10 2008

Classification: 21 CFR 892.1600

Product Code: 90 IZI

Classification: Class II

Manufacturer:
Novadaq Technologies Inc.
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Contact Name:
Allison Manners
Vice President, Regulatory and Clinical Affairs

Date 510(k) Summary Prepared: October 29, 2007

Legally Marketed Predicate Devices:

The Novadaq® SPY Fluorescent Imaging System (SPY System) with the SP2000 Imaging Device had received initial FDA 510(k) clearance for market use during coronary artery bypass graft (CABG) surgery in January 2005 (K042961). Subsequent 510(k) clearance was obtained in May 2006 (K060867) for a labeling change, followed by a clearance for use in plastic, micro- and reconstructive surgery in January 2007 (K063345), and a clearance for use of an alternative brand of fluorescent ICG agent in coronary artery bypass surgery in May 2007 (K071037), as well as in the plastic, micro-, and reconstructive surgery in September 2007 (K072222), pending drug approval.

The Leica FL800 had received FDA 510(k) clearance for market in September 2006 (K061871). The Leica FL800 is intended for use to allow neurosurgeons to view blood flow.

Device Description:

The SPY Fluorescent Imaging System is currently cleared for use:

- For intra-operative visual assessment of the coronary vasculature and bypass grafts during CABG surgery.
- As 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.

In addition to these cleared indications for use, a traditional 510(k) submission is currently under review (K071619) at the FDA with expected default clearance date of October 31, 2007. That submission revises the indication for use in CABG surgery, and seeks clearance for the use of SPY System to provide fluorescent images for the visual assessment of blood flow in vessels and related tissue perfusion during cardiovascular surgical procedures.

The Novadaq® Technologies SPY® Fluorescent Imaging System used in plastic, micro, and reconstructive surgery indication consists of 2 components:

- the SP2001 Imaging Device
- the SPY Paq®

The SPY Paqs are available in 2 configurations dependent on the intended indication for use[1]. Each SPY Paq contains sufficient number of ICG, custom sterile drapes called Novadrape®, and diluent for 6 imaging procedures. Each configuration of SPY Paq has a unique part number assigned to it, and different Instructions for Use exist for the two types of SPY Paqs. The different Instructions for Use also have unique part numbers for ease of assembly of the Paqs and guidance for the end user.

<u>The SP2000 Imaging Device</u>

The SP2000 Imaging Device consists of an imaging head containing a charge coupled device (CCD) camera, a laser light source, motion sensor, and distance sensor attached via an articulating arm to a mobile cart. The mobile cart contains

[1] Novadaq provides ICG as it is sold by the manufacturer and does not adulterate the integrity of the original packaging or labeling. IC-Green™ (Akorn, Inc.) is packaged in a kit that contains 6 x 25 mg vials of ICG and 6 diluents used to dissolve the ICG. Two IC-Green kits constitute a 6 procedure SPY Paq for the plastic, micro-, and reconstructive surgery indication, with two vials of ICG and two diluents being used in imaging throughout a surgical procedure. Two vials of ICG are required for each imaging procedure to secure a sufficient amount of ICG necessary for the recommended number and volumes of injections. Additionally, IC-Green solution has to be used within 6 hours from reconstitution, and the duration of complex plastic, micro-, and reconstructive surgical procedures often exceeds 6 hours. This results in the time separation between the initial and final sets of injections exceeding 6 hours, necessitating reconstitution of a second IC-Green vial.

a flat panel display, a computer with keyboard and optical mouse, an electronics enclosure, and a printer.

The SPY® System provides the surgeon with the capability to view, record, and replay fluorescent images of blood flow in vessels and organs. A laser light source is used to illuminate the area of interest. In order to obtain the images, ICG is injected intravenously through the central or peripheral venous line, bypass pump, cardioplegia line, or down a coronary graft. While the ICG is passing through the vessels, the absorption of laser light causes excitation of the ICG dye, followed by the emission of infrared energy. A CCD camera of the SP2000 Imaging Device captures the infrared emission, resulting in a fluorescent image of blood flow and related tissue perfusion. These images are used to evaluate the integrity of native and grafted vasculature and blood flow in the organs.

There have been no significant changes or modifications made to the SP2000 Imaging Device since the original 510(k) clearance in January 2005 premarket notification 510(k) K042961, the 510(k) premarket notification K060867 submitted for a label change for this device, the 510(k) clearance K063345 for use in the plastic, micro- and reconstructive surgery, and the clearances K071037 and K072222 for use of an alternative brand of fluorescent dye – ICG PULSION® in May 2007 and September 2007, pending drug approval.

The SP2001 Imaging Device

The SP2001 Imaging Device represents minor modifications of the SP2000 Imaging Device:

- The maximum recording time for image sequences captured has been extended to 60 seconds from the 34 seconds of the SP2000 Imaging Device. This modification has been carried out to permit the users to observe the entire cycle of blood flow in the area of interest under imaging; namely the arterial inflow, the perfusion, and the venous outflow.
- An ability to move the SP2001 camera head in horizontal plane during image sequence acquisition has been implemented. This modification has been carried out to permit the users to image the area larger than the 7.6 cm x 7.6 cm which is imaged by a stationary camera of the SP2000 Imaging Device. This feature is very desirable, given that a flap can be large or extended.
- A variable Laser Power Attenuator has been added to the device to permit laser illumination at power levels **lower or equal to** the laser power level of the SP2000 Imaging Device. This modification has been carried out to permit the SP2001 operators to lower laser intensity, in case the signal from the area of interest would be saturating the sensitivity of the camera.
- New HELIOS™ software has been developed to support the SPY System in its plastic, micro-, and reconstructive surgery indication. The structure and workflow of the HELIOS software is based on the cleared DaqPac

software. The HELIOS software concentrated on the providing the user with the most suitable interface and it did not alter the way that the device is used.

The modifications of the SP2000 Imaging Device were introduced to provide the end users the increased functionality for using the SPY System in the plastic, micro-, and reconstructive surgery.

It is demonstrated in Section 10 – Device Description that the modifications do not introduce any additional or new concerns regarding the safety and use of the device.

SPY® Systems intended for use solely in cardiovascular surgery utilize the SP2000 Imaging Device. SPY Systems intended for use in the plastic, micro-, and reconstructive surgery utilize the SP2001 Imaging Device.

Proposed Intended Use of the SPY System:

This premarket 510(k) notification is being made to obtain clearance for the device modification.

The currently cleared and proposed indications for use in CABG and cardiovascular surgery, as well as in plastic, micro-, and reconstructive surgery, and cardiovascular surgery are not being amended in any way with this submission.

The SPY Fluorescent Imaging 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 in plastic, micro- and reconstructive surgical procedures.

Testing:

Animal studies, human experience and in vitro testing were conducted to support the safe and effective use of the SPY System in its original premarket notification 510(k) application (K042961).

The information contained within this Traditional premarket notification 510(k) demonstrates the utility of the SPY System in plastic, micro-, and reconstructive surgery. This information has been previously submitted together with the cleared 510(k) notifications K063345 and K072222.

In Vitro Testing:

Testing of the SPY System was completed in conformance with the following standards. The SPY System successfully met all of the requirements for these standards.

1. Electrical per IEC 60601-1 and UL2601-1
2. Electromagnetic Compatibility per IEC 60601-1-2
3. Light Emitting Laser Products per 21 CFR 1040
4. Safe Use of Lasers in Health Care Facilities per ANSI Z136.3
5. American National Standard for Safe Use of Lasers per ANSI Z136.1

In Vivo Testing:

The SPY® System is commercially available in the United States of America, Japan, Europe, and Canada. To date, the SPY System has been used in over 7000 vascular procedures in humans and there have been no reports of adverse acute or long-term cellular, renal or hepatic effects. The data from intra-operative imaging in CABG, cardiovascular, as well as in plastic, micro-, reconstructive surgery demonstrated the clinical utility of the device in producing high quality and resolution images of the entire vascular bed of the area of interest.

Results from the use of the SPY System has been the subject of 15 peer reviewed journal articles, 13 related to its use in cardiac surgery and 2 related to its use in transplantation kidney and liver surgeries. Please refer to the bibliography in Section 19 - Clinical for a listing of all relevant journal articles.

The literature reports that the SPY System was able to non-invasively, quickly and safely identify 17 conduits in 311 patients that required revision during the surgical procedures. In all cases the lack of patency was visualized clearly by the SPY System using doses of ICG well below the maximum dose approved for human use. It allowed the surgeon to revise the graft, decreasing subsequent myocardial infarctions and the morbidity and mortality associated with poor graft patency. Cardiac, renal and hepatic functions were monitored during use of the SPY System and there were no reported adverse effects.

To support the original traditional 510(k) premarket notification, the system was used in six pig studies. These studies demonstrated that:

1) It was possible to acquire high quality images in a simple and reproducible manner using small doses of ICG well below the concentrations approved for human use.
2) It was possible to perform multiple imaging sequences with no detrimental effects on heart function, coronary flow or peripheral pressure.
3) It was possible to acquire images with no increase in myocardial tissue temperature.
4) It was possible to visualize all of the coronary beds with high quality images even when the heart was in a vertical position for visualizing posterior arteries.

Therefore, in totality, the in vivo evidence shows that:

1. The exposure for the SP2001 Imaging Device at the imaging distance of 30 cm is 31.2 mW/cm^2 which is far below the maximum permissible exposure (MPE) of 326 mW/cm^2 established by ANSI for exposure to the skin. The exposure remains below the MPE value as long as the camera head of SP2001 is not advanced closer than 5 cm from the region of interest imaged. The extension of the recording time to 60 seconds does not affect the MPE value.
2. Use of the SPY® System does not cause any thermal damage to the area of interest, even after repeated imaging sequences.
3. For the heart, there were no changes in electrocardiograms or arterial pressures during and/or following the use of SPY System.
4. There were no acute or long-term cellular effects of using the SPY System.
5. There were no acute or long-term renal or hepatic effects of using the SPY System.
6. The SPY System was able to acquire high quality images of the entire vascular bed on each area of interest.
7. The SPY System is capable of imaging through the skin to provide a visual assessment of dermal and subdermal blood flow.

Conclusions:

The documentation provided in this Traditional 510(k) Notification demonstrates that the SP2001 modification of the SP2000 Imaging Device component SPY Fluorescent Imaging System results in a device equivalent to predicate devices. The SPY System including the SP2001 Imaging Device can be 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 10 2008

Ms. Allison Manners
Vice President, Regulatory and Clinical Affairs
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Mississauga, Ontario, L4W 4L5
CANADA

Re: K073088
Trade/Device Name: SPY® Fluorescent Imaging System: SP2001 Imaging Device
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: October 30, 2007
Received: November 1, 2007

Dear Ms. Manners:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073088

Device Name: SPY® Fluorescent Imaging System: SP2001 Imaging Device

Indications for Use:

The SPY Fluorescent Imaging 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 in plastic, micro- and reconstructive surgical procedures.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073088