

510(k) Summary

Trade Name: SPY® Intra-operative Imaging System

Device Model Number: SP2001

Common Name: Fluorescent Angiographic System

Classification: 21 CFR § 892.1600

Product Code: 90 IZI

Classification: Class II

Manufacturer: Novadaq Technologies Inc.
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Date 510(k) Summary Prepared: February 9, 2010

Legally Marketed Predicate Devices:

The Novadaq® SPY® Intra-operative Imaging System (SPY System), device model SP2000, received initial Food and Drug Administration (FDA) Premarket Notification 510(k) (510(k)) clearance for market for 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 to inject the imaging agent indocyanine green (ICG) directly into the graft, followed by a clearance for use in plastic, micro- and reconstructive surgery in January 2007 (K063345). Clearances for use of an alternative brand of fluorescent ICG agent in coronary artery bypass surgery and plastic, micro-, and reconstructive surgery were obtained in May 2007 (K071037) and September 2007 (K072222), respectively. A labeling change to broaden the use of the SPY system in cardiovascular surgical procedures, from the narrower indication for use in CABG surgery, was cleared in November 2007 (K071619).

The SPY Intra-operative Imaging System, device model SP2001, was subsequently cleared for use in plastic, micro- and reconstructive surgery in January 2008 (K073088) and for organ transplant surgeries in January 2008 (K073130).

Novadaq believes that the SPY System described in this application is also substantially equivalent to the previously cleared Siemens AXIOM Artis U system (K040675). Both systems share the same product code (90 IZI) and regulatory classification (21 CFR § 892.1600). The indications for use of the AXIOM Artis U system which include imaging procedures of the gastrointestinal (GI) system are also comparable to the proposed indications for use in this submission.

Device Description:

The SPY System, device model no. SP2001 is currently cleared for the following 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.
- The SPY Fluorescent Imaging System is intended to intra-operatively enable surgeons to visually assess blood flow and related tissue perfusion during organ transplant procedures.

The SPY System consists of two components:

- the SP2001 Imaging Device
- the SPY Paq®

The SPY System utilizes the fluorescent imaging agent ICG. 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.) and ICG-PULSION® (Pulsion Medical) are packaged in a kit that contains 6 x 25 mg vials of ICG and 6 diluents used to dissolve the ICG. Both brands of ICG have been approved for pediatric use.

SPY Paqs are available in 2 configurations dependent on the intended indication for use. In organ transplant procedures, the SPY Paqs contain 6 sterile custom Novadrapes® and 1 kit of ICG. For plastic, micro- and reconstructive surgery procedures, the SPY Paqs contain 6 sterile drapes and 2 kits of ICG. This is due to the fact that plastic, micro- and reconstructive surgeries are typically longer surgeries, and ICG is only labeled with a 6 hour shelf life once reconstituted. Each SPY Paq contains sufficient number of ICG vials, custom Novadrapes, and diluents for 6 imaging procedures. For the proposed indication for use during gastrointestinal procedures, the SPY Paq will be the same as that used for organ transplant procedures, containing 6 sterile drapes and 1 kit of ICG. 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.

The SP2001 Imaging Device consists of an imaging head containing a camera, a laser light source, and a distance sensor attached to a mobile cart via an articulating arm. The mobile cart contains a flat panel monitor, a computer with keyboard and mouse, an electronics enclosure, and a printer.

ICG has been cleared in the previous 510(k) applications to be administered intravenously through the central/peripheral venous line, cardioplegia line, as well as down the coronary graft or bypass pump. While ICG distributes through the vessels or tissues, absorption of laser light at 808 nm causes excitation of the ICG followed by emission of infrared energy at a wavelength of 830 nm. This results in a fluorescent image of the blood vessels and related tissue perfusion. A CCD camera with an 830 nm optical band-pass filter captures the images. Image sequences, up to 60 seconds in duration, are displayed on the monitor and recorded on the computer hard drive. The image sequences can be exported to a CD, DVD, memory stick or Ipod. The camera head can be moved in the horizontal plane during image sequence acquisition. Once the image is captured, the laser automatically shuts off.

There have been no substantial changes to the SPY System, Model SP2001, for this 510(k) application that impacts its fundamental scientific premise from previously clearances.

Proposed Intended Use of the SPY System:

This Traditional Premarket Notification 510(k) submission is being made to expand the Indications for Use for the SPY System during GI surgical procedures. The currently cleared indications for use in cardiovascular surgery (K071619), in plastic, micro- and reconstructive surgery (K073088), and organ transplant surgeries (K073130) are not affected in any way with this submission.

The data contained within this 510(k) application are being presented to support the following proposed Indications for Use:

- The SPY System is intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during gastrointestinal 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 Premarket Notification 510(k) submission (K042961).

The information contained in this 510(k) submission demonstrates the utility of the SPY System during GI surgical procedures in addition to the previously cleared indications.

***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.

- Electrical per IEC 60601-1, IEC 60601-1-4 and UL2601-1
- Electromagnetic Compatibility per IEC 60601-1-2
- Light Emitting Laser Products per 21 CFR 1040
- Safe Use of Lasers in Health Care Facilities per ANSI Z136.3
- 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, Canada, Israel, and Russia. To date, the SPY System has been used in over 10,000 surgical 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, other procedures, as well as in plastic, micro-, reconstructive and organ transplant surgeries demonstrated the clinical utility of the device in producing high quality and resolution images of the entire vascular bed of the area of interest.

To date, the SPY System has been described in over 30 publications. Refer to Section 18: Performance Testing – Clinical. Most have reported the use the SPY System in adult populations. One publication describes its use in pediatric cardiac surgery.

To support the original 510(k) notification, the SPY 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.

This current 510(k) submission contains clinical performance data that support the use of the SPY System during GI surgical procedures. All cases were conducted under the attending surgeons' medical judgment as part of the reconstructive clearance for the device. The examples are not meant to be all encompassing of the clinical utility of the SPY System in all GI surgical procedures, but illustrate the safety and effectiveness of SPY imaging in this system throughout the GI tract from the esophagus to the anus. The quality of the SPY images obtained is comparable to those acquired with the SPY System for previously cleared applications. In all cases, ICG was administered well below the 2 mg/kg limit and consistent with the previously cleared indications for ICG use as part of the SPY System. To date, there have been no reports of adverse events associated with the SPY imaging procedure, including ICG injection.

The data presented here support the proposed Indications for Use without introducing any new concerns related to safety and effectiveness of the SPY System.

In summary, 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/cm² which is far below the maximum permissible exposure (MPE) of 326 mW/cm² 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.
- 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 testing demonstrates that the SPY System is equivalent to predicate devices and can be used as intended to provide a visual assessment of arterial and venous blood flow and related tissue perfusion during GI surgical procedures. The visual assessment provides an adjunctive method for the evaluation of flow in native and co-joined vessels, tissue perfusion, and related tissue-transfer circulation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 23 2011

Re: K100371

Trade/Device Name: SPY[®] Intra-operative Imaging System .
Regulation Number: 21 CFR §892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: December 31, 2010
Received: January 5, 2011

Dear Ms. Manners:

This letter corrects our letter of February 4, 2011.

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). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the SPY PAQ consumable kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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.

In addition, we have determined that your device kit contains indocyanine green (ICG) fluorescent imaging agent, which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 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" (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.

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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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100371

Device Name: SPY® Intra-operative Imaging System

Indications for Use:

The SPY System is intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during gastrointestinal surgical procedures.

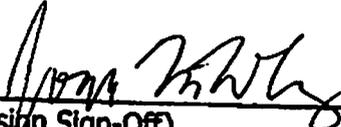
Prescription Use X
(Part 21 CFR 801 Subpart D)

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, Gastro-Renal, and
Urological Devices
510(k) Number K100371

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