K071619
p1/5

510(k) Summary

Trade Name: SPY® Fluorescent Imaging System

Model Number: SP2000

Common Name: Fluorescent Angiographic System

Classification: 21 CFR 892.1600

Product Code: 90 IZI

NOV 0 9 2007

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 31, 2007

Legally Marketed Predicate Devices:

The Novadaq® SPY Fluorescent Imaging System (SPY System) had received FDA 510(k) clearance for market in January 2005 (K#042961), subsequent 510(k) clearances for a labeling change in May 2006 (K#060867) and use of an alternative brand of fluorescent dye in May 2007, pending drug approval (K#071037).

The Leica FL800 had received FDA 510(k) clearance for market in September 2006 (K#061871). The Leica FL800 is intended for use to allow neurosurgeons to view blood flow.

Device Description:

The SPY Imaging System: SP2000 is currently cleared for use for intra-operative visual assessment of the coronary vasculature and grafts during coronary artery bypass graft (CABG) surgery.

The Novadaq® Technologies SPY® Fluorescent Imaging System consists of 2 components:

- the SP2000 Imaging Device; and
- the SPY Paq®.

The SPY Paq constitutes a 6 procedure kit. Each SPY Paq contains sufficient numbers of custom sterile drapes, called Novadrape® and ICG and diluent to carry out 6 cardiovascular imaging procedures. Novadaq provides the 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 an IC-Green kit that contains 6 x 25 mg vials of ICG along with 6 x 10 ml ampules of Aqueous Solvent.

The SP2000 Imaging Device

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 a flat panel display, computer, electronics enclosure and printer.

The SPY System provides the surgeon with the capability to view record and replay fluorescent images of blood flow in vessels and bypass grafts of the heart. A laser light source is used to illuminate the area of interest. ICG is injected intravenously through the central venous line, bypass pump, cardioplegia line and coronary graft and while it is passing through the vessels, the absorption of laser light causes excitation of the dye followed by emission of infrared energy. The result is a fluorescent image of blood flow and related tissue perfusion in the vessels. A CCD camera captures the image. These images are used to evaluate the integrity of the coronary vasculature and blood flow in the heart and bypass grafts.

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) K#042961, or for the 510(k) submitted for a label change for this device, K#060867.

This 510(k) submission describes a proposed change in intended use that does not alter the devices fundamental scientific technology or characteristics in anyway.

Proposed Intended Use of the SPY System:

This premarket notification 510(k) application is being made to revise the indications for use.

In addition to the already cleared indication for use of the SPY® System, the System is also intended to provide fluorescent images for the visual assessment of blood flow in vessels and related tissue perfusion during cardiovascular 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 (K#042961).

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 4000 CABG procedures in humans and there have been no reports of adverse acute or long-term cellular, renal or hepatic effects. Along with the data from intra-operative imaging in CABG surgery, the use of the SPY System in plastic, micro- or reconstructive and other vascular surgery demonstrates the clinical utility of the device in producing high quality and resolution images of the entire vascular bed of the point of interest.

The SPY® System was originally cleared by the FDA for use in intra-operative visual assessment of the coronary vasculature and bypass grafts during CABG surgery. During the period that the SPY System has been placed in surgical units, several cardiovascular surgeons have made use of the SPY System for purposes other than the original indication. The present application seeks clearance for this broader range of cardiovascular indications, including but not limited to that already cleared for CABG surgery. Specifically, the SPY System has been used to:

- Assess the coronary vasculature and related myocardial perfusion
  - To assess delivery of cardioplegia
  - To assess the impact of procedures involving the aortic valve and/or ascending aorta on coronary artery function
  - Following heart transplant
- Confirm blood flow through vessels branching off the aorta following surgical procedures on the descending aorta
- Confirm blood flow through vessels following vascular procedures
  - Carotid endarterectomy
  - Peripheral vascular procedures
- Assess perfusion of extremities without skin incision

Examples and the rationale for each of these indications are described in more detail in Section 19 of this traditional 510(k) premarket notification.

Results from the use of the SPY System has been the subject of 12 peer reviewed journal articles, 10 related to its use in cardiac surgery and 2 related to its use in transplantation surgeries, namely kidney and liver. 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 that approved for human use, allowing the surgeon to revise the graft thus decreasing subsequent myocardial infarctions and the morbidity and mortality associated with poor graft patency. Cardiac, renal and hepatic function were monitored during use of the SPY System and there were no reported adverse effects.

To support the original premarket notification 510(k) application, 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; and
3) it was possible to acquire images with no increase in myocardial tissue temperature; and
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, the *in* vivo evidence shows that:

1. The exposure for the SPY® System is 35 mW/cm^2 which is far below the maximum permissible exposure of 327 mW/cm^2 established by ANSI for exposure to the skin.
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 SPY use.
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 above testing demonstrates that the SPY Fluorescent Imaging System is safe and effective in imaging blood flow indicative of tissue perfusion, and related tissue-transfer circulation in cardiovascular surgical procedures and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 0 9 2007

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Re: K071619
Trade/Device Name: SPY® Intraoperative Imaging System
Regulation Number: 21 CFR 892.1600
Regulation Name: Fluorescent angiography system
Regulatory Class: Class II (two)
Product Code: IZI
Dated: October 31, 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 (240) 276-0120. 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,

B. Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071619

Device Name: SPY® Imaging System: SP2000

Indications for Use:

The SPY Fluorescent Imaging System is intended to provide fluorescent images for the visual assessment of blood flow in vessels and related tissue perfusion during cardiovascular 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071619