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510(k) Summary

Trade Name: SPY® Intra-operative Imaging System

Model Number: SP2000

MAY 10 2007

Common Name: Fluorescent Angiographic System

Classification: 21 CFR 892.1600

Product Code: 90 IZI

Classification: Class II

Manufacturer: Novadaq® Technologies Inc.
2585 Skymark Avenue
Suite 306
Mississauga, Ontario
Canada
L4W 4L5
905.629.3822 ext. 240

Contact Name: Allison Manners
Vice President – Regulatory and Clinical Affairs

Date 510(k) Summary Prepared: April 9, 2007

Legally Marketed Predicate Devices:

The Novadaq SPY Imaging System had received FDA 510(k) clearance for market in January 2005 (K042961) and subsequently received 510(k) clearance for a labeling change in May 2006 (K060867).

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 Intra-operative Imaging System consists of 2 components:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2007

Ms. Allison Manners
Vice President, Regulatory and Clinical Affairs
Novadaq Technologies Inc.
2585 Skymark Avenue Suite 306
Mississauga, Ontario Canada L4W 4L5

Re: K071037
Trade Name: SPY® Intraoperative Imaging System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II (two)
Product Code: IZI
Dated: April 11, 2007
Received: April 12, 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). You may not market this device, however, until such time as the new drug application for the drug indocyanine green manufactured by PULSION® Medical Systems is approved for human use by The Center for Drug Evaluation and Research, FDA. When the device is marketed, it will be subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (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.

However, you are responsible to determine that the medical devices you use as components in the SPY® Intraoperative Imaging System 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.

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); 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 510(k) premarket notification subject to approval of the indocyanine green manufactured by PULSION® Medical Systems. 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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

Indications for Use

510(k) Number (if known): K071037

Device Name: SPY® Intra-operative Imaging System: SP2000

Indications for Use:

For use in intraoperative visual assessment of the coronary vasculature and bypass grafts during coronary artery bypass (CABG) surgery.

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 K071037