510(k) Summary

SEP 1 7 2008

K 081792

Date Summary Prepared: June 19, 2008

Trade Name: SPY® Analysis Toolkit

Common Name: Medical Image Processing Software

Classification: Class II device

Classification Name: System, Image Processing, Radiological

CFR Classification: 21CFR892.2050

Product Code : LLZ

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

Legally Marketed Predicate Devices:

The Novadaq SPY Analysis Toolkit utilizes the same technological characteristics, has the same intended use and is substantially equivalent to at least three predicate devices previously cleared for commercial distribution. The enclosed information for three of these demonstrates substantial equivalence. These commercial products include:

1. **American Radiologist Network xViewNet** cleared for market via K080290
   Trade Name: xViewNet
   Product Code: LLZ
2. **Siemens syngo TrueD**, Model VC10A cleared for market via K061671
   Trade Name: Siements *syngo* TrueD, Model VC10A
   Product Code: LLZ
3. **Biotronics3D 3Dnet Suite** cleared for market via K063107
   Trade Name: Biotronics3D 3Dnet Suite
   Product Code: LLZ

In each of these software devices, including the SPY Analysis Toolkit, the analysis software is used to receive images from various sources which can then be stored, communicated, manipulated, annotated, measured, compared, displayed and reported within the intended systems or at individual work stations with the appropriate configurations.

Detailed information regarding each of these predicates, including 510(k) Summaries and Indications for Use can be found in Section 21– Predicates, of this Traditional 510(k) Pre-market Notification submission.

Device Description:

The SPY® Analysis Toolkit is a separate companion application to the SPY Intra-operative Imaging System's (SPY System) software, which is currently cleared for use in cardiovascular, plastic and reconstruction, and organ transplant surgeries. The Analysis Toolkit is capable of working cooperatively, as an accessory plug-in feature, with the SPY software or standalone on a physician's desktop computer. The Analysis Toolkit is not real-time.

Novadaq's SPY System allows surgeons (including cardiovascular, plastic and reconstructive, and transplant) to produce real-time images of blood vessels, surrounding tissue and related perfusion of those tissues/organs during various types of surgeries. The Analysis Toolkit provides a set of clinical image analysis tools and makes them available to clinicians for either intra-operative post image acquisition or retrospective analysis. The ultimate goal of analysis will be to provide surgeons with another parameter, in addition to standard of care information, including data from other imaging modalities, for use in pre-operative decision-making and post-operative evaluation of results as an input to post-operative care.

The SPY Analysis Toolkit is a plug-in module to the SPY Imaging Device and does not have any control over the device or the previously cleared software. The SPY Analysis Toolkit is an accessory software feature designed and developed to work with images acquired on the SPY System, models SP2000 and SP2001. The SPY Analysis Toolkit has no capability to modify in any way the underlying images previously acquired intra-operatively by the SPY System. The resolution and the quality of the images captured by the SPY System and analyzed by the SPY Analysis Toolkit remain the same.

The SPY Analysis Toolkit application is for viewing, manipulation, measurement and comparison of medical image sequences produced at single or multiple time-points by the SPY System. Entire image time-sequences are processed for viewing using a variety of analytical algorithms that provide visual or numerical results.

The Analysis Toolkit can also accept DICOM and AVI images independent of the SPY device for post-operative analysis.

Proposed Intended Use / Indications for Use:

The SPY Analysis Toolkit is a separate companion software application to the SPY Intra-operative Imaging System and is intended as a display, analysis, and comparison tool for the interpretation of SPY images by trained healthcare professionals including cardiovascular, plastic & reconstructive, and organ transplant surgeons.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate images. The SPY Analysis Toolkit is a complement to the SPY procedures.

Testing:

The SPY Analysis Toolkit was designed and developed with the input from experienced SPY System users. The feedback and input was from all disciplines currently cleared to use the SPY System, in cardiovascular, plastic and reconstructive, organ transplant surgeries. The input was captured in a written and approved Software Requirement Specifications Document. The SPY Analysis Toolkit has been developed in a manner

consistent with accepted standards for software development, including both unit and system integration testing protocols.

Scanned image datasets from the various disciplines were used as input for testing of the software functionalities in accordance with the Software Development Plan. A full description of the software functionality, device hazard analysis, software requirements, and verification and validation protocols and testing can be found in Section 16 – Software, of this submission.

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by trained professionals allowing sufficient review for identification and intervention in the event of a malfunction. Device output and analysis is not real-time and is only used to indicate the appropriateness of a referral or surgical decision. Additional clinically relevant parameters / tests, including data from alternative imaging modalities, must be used in the any surgical intervention. The device does not impact the quality or status of the original acquired data.

Conclusions:

The SPY Analysis Toolkit has the same intended use and similar technological characteristics as the previously noted predicate software devices. As demonstrated within this Traditional 510(k) pre-market notification, there are no substantial differences between the SPY Analysis Toolkit and the stated predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2008

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

Re: K081792
Trade/Device Name: SPY Analysis Toolkit
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 23, 2008
Received: June 25, 2008

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) 276-0115. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K081792

Device Name: SPY Analysis Toolkit

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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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081792

Concurrence of CDRH, Office of Device Evaluation (ODE)