DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Combination Products
15800 Crabbs Branch Way
Suite 200, HFG-3
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

October 8, 2004

Arun Menawat, CEO and President
Rick Mangat
Novadaq Technologies, Inc.
2585 Skymark Avenue
Suite 306
Mississauga, Ontario, Canada
L4WL5

Re: Request for Designation
SPY™ Intra-Operative Imaging System
Our file: RFD 2004.042
Dated: August 13, 2004
Received and filed: August 13, 2004

Dear Mr. Menawat and Mr. Mangat:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the SPY™ Intra-Operative Imaging System that you submitted on behalf of Novadaq Technologies, Inc. on August 13, 2004, and the supplemental information you submitted by email on September 15, 2004. The Office of Combination Products (OCP) filed the RFD on August 13, 2004. As explained below, we conclude that the SPY™ Intra-Operative Imaging System is a combination product that will be reviewed and regulated by the Center for Devices and Radiological Health under the device provisions of the Federal Food, Drug, and Cosmetic Act (the act).

Description of the Product

According to the RFD, the SPY™ Intra-Operative Imaging System is intended to enable surgeons to visualize the coronary vasculature and bypass grafts intraoperatively during coronary artery bypass surgery. The System works by administering a small amount of indocyanine green (ICG) to the patient through the central venous line, directly into the bypass pump or via the cardioplegia line. Once the ICG is distributed through the coronary vasculature, the heart's surface is illuminated by a laser light. The RFD states that absorption of the laser light excites the ICG, causing the emission of near infra-red energy,

resulting in a fluorescent image of the coronary blood vessels and bypass grafts, which can be stored on a floppy disk or CD.

The SPY™ System consists of the laser light source, the camera, and the apparatus to record the images on a floppy disk or CD. The System also includes [ ] to be used in the procedure and a single use vial of ICG. ICG is currently approved under new drug applications for cardiac thermodilution procedures, hepatic function and liver blood flow, as well as for ophthalmic angiography.

The RFD states that Novadaq will [ ] The supplemental information submitted on September 15, 2004 states that [ ] NDA 11525. Furthermore, according to the supplemental information, [ ].

Novadaq submitted a request for designation for a very similar imaging system in June 2001. In response to that RFD, FDA's Office of the Ombudsman determined that the imaging system was a combination product; the ICG was to be reviewed and regulated by CDER under a new drug application and the device components of the system were to be reviewed and regulated by CDRH under the device provisions of the act. The current RFD requests that the SPY™ Intra-Operative Imaging System be reviewed and regulated under one marketing application rather than two. The RFD recommends that CDRH have the responsibility for reviewing and regulating of the SPY™ System under the device provisions of the act.

Product Classification: Combination Product

The SPY™ Intra-Operative Imaging System consists of device components such as the laser light, the camera, apparatus to record the images on a floppy disk or CD, and [ ] in combination with the drug ICG. Therefore, we conclude that the SPY™ Intra-Operative Imaging System is a combination product within the meaning of section 503(g) of the Act and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(2). In accordance with section 503(g)(1) of the Act and 21 CFR § 3.4, assignment of a lead Center to conduct the review of a combination product is based on the Agency's determination of the product's primary mode of action.

Assignment of Lead Center: CDRH

We have considered the information in the RFD and supplemental information, and discussed the issues with staff in CDRH and the Center for Drug Evaluation and Research (CDER).

We have determined that the primary mode of action of this product is the viewing, recording, and replaying of images, which is attributable to the device components of the system. The drug plays a secondary role, facilitating the ability of the device components to achieve the intended use of the system. Accordingly, we are assigning the product to CDRH for premarket review and regulation under the medical device provisions of the act.

We have also made preliminary determinations about other regulatory requirements that will apply to your combination product. These are subject to further review by the agency. The combination product will be subject to manufacturing and adverse event reporting requirements applicable to devices (21 CFR Parts 814 and 803, respectively). However, current good manufacturing practices for drugs will apply to the manufacture of ICG (21 CFR Parts 210 and 211). FDA recently published a draft guidance document "Current Good Manufacturing Practice for Combination Products, available at http://www.fda.gov/oc/combination/default.htm. Any clinical investigation of the combination product is subject to the Investigational Device Exemption (IDE) requirements found in 21 CFR Part 812. We encourage you to discuss with CDRH these and other regulatory requirements applicable to your product.

CDRH and CDER will collaborate on the issue of the safety of using ICG as contemplated in the SPY™ Imaging System. CDRH may consult with CDER on any other issue as appropriate during the review of the SPY Imaging System.

CDRH's Division of Cardiovascular Devices, Cardiac Electrophysiology & Monitoring Devices Branch will have lead responsibility for the combination product's premarket review and regulation. For further information about review requirements, please contact Elias Mallis, Chief, Cardiac Electrophysiology & Monitoring Devices Branch, at 301-443-8517. Please include a copy of this letter in your initial submission to CDRH.

You may request reconsideration of the classification of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or for any other questions about this letter, please contact me at 301-427-1934.

Sincerely,

Suzanne O'Shea for

Mark D. Kramer
Director
Office of Combination Products

cc: Elias Mallis