MAR 2 2 2013

510(k) Summary
For the Novadaq Disposable Rigid Scope Introducer

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Summary Date: March 14, 2013

Applicant:
Novadaq Technologies Inc.
13155 Delf Place, Unit 250
Richmond, British Columbia
Canada V6V 2A2
Tel: (604) 232 9861

Contact Name:
Tim Verspagen
Sr. Manager, Regulatory Compliance
Tel: (604) 232-9861 Ext. 240
Fax: (604) 232-9641

Trade Name: Disposable Rigid Scope Introducer

Classification Name: Endoscopic Access Overtube

Classification: 21 CFR § 876.1500

Product Code: 78 (FED)

Classification: Class II

Predicate Devices:
K092221 Colonic Splinting Overtube
(US Endoscopy)

K033954 Shape Locking Endoscopic Overtube
(USGI Medical Inc.)

K770291 Disposable Rigid Sigmoidoscope
(Welch Allyn)

Device Description:

The single-use Disposable Rigid Scope Introducer is used in conjunction with a laparoscope to allow visual examination of the rectum and distal portions of the colon. When used with the laparoscope, the Disposable Rigid Scope Introducer and laparoscope are advanced into the rectum under visual guidance to a maximum insertion length of 25cm. An insufflation port is provided as part of the Endoscopic Introducer to allow insufflation of the rectum and lower colon.

Indications for Use:

The Novadaq Disposable Rigid Scope Introducer is intended to facilitate passage of a laparoscope through the anus allowing visual examination of the rectum and distal portions of the colon.

Predicate Device Technological Comparison Summary:

Considered in combination, the predicate devices are used to provide an introduction pathway to enable visual examination of the rectum and distal colon by also providing a channel for insufflation.

The predicate devices and the Disposable Rigid Scope Introducer are similar in shape and materials. The effect of use of the Disposable Rigid Scope Introducer and the predicate devices on the patient is the same. With respect to mechanical dimensions, the diameters of the devices are similar, while the length of the Disposable Rigid Scope Introducer is less than the predicate device as it is intended to be inserted a shorter distance.

Similar to one of the predicate devices, the Disposable Rigid Scope Introducer provides a channel to insufflate the rectum and distal colon which enables the visual examination.

Any additional indications for use claimed by the predicate device do not affect the safe and effective use of the Disposable Rigid Scope Introducer when used according to its instructions for use.

Nonclinical Tests:

The device safety and performance were verified by tests conducted by Novadaq Technologies and accredited third party laboratories. Standards used / relied upon for testing are:

- ISO 10993-1:2009
- ISO 8600-1 Second Ed.
- ISO 8600-4 First Ed.

Clinical Performance Data:

For clinical evaluation, an exhaustive literature search was conducted according to written protocol. The clinical evaluation report is based on clinical data obtained from review of clinical literature and clinical experience from adverse events database.

Data presented in the clinical evaluation report provide evidence that supports the safety and performance claims made for the Endoscopic Introducer.

Safety & Effectiveness:

It has been shown in this 510(k) submission that any differences in intended use or technological characteristics between the Disposable Rigid Scope Introducer and the referenced predicate device do not raise any questions regarding its safety and effectiveness. The Endoscopic Introducer, as designed, manufactured and used according to its labeled intended use is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

Novadaq Technologies, Inc.
% Mr. Tim Verspagen
Sr. Manager Regulatory Compliance
13155 Delf Place, Unit 250
RICHMOND BRITISH COLUMBIA
CANADA V6V 2A2

Re: K123013
Trade/Device Name: Disposable Rigid Scope Introducer
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: February 19, 2013
Received: February 20, 2013

Dear Mr. Verspagen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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" (21CFR 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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
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): K123013

Device Name: Disposable Rigid Scope Introducer

Indications for Use:

The Novadaq Disposable Rigid Scope Introducer is intended to facilitate passage of a laparoscope through the anus allowing visual examination of the rectum and distal portions of the colon.

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)

Herbert P Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123013