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

NDO Surgical, Inc.
Mr. Jeff Cerier
Director of Product Development
125 High Street, Suite 7
Mansfield, MA 02048

JUL 27 2015

Re: K002018
Trade/Device Name: NDO Surgical Overtube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated (Date on orig SE ltr): June 29, 2000
Received (Date on orig SE ltr): July 3, 2000

Dear Mr. Cerier,

This letter corrects our substantially equivalent letter of August 17, 2000.

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 contact 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. 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,

Benjamin R. Fisher -S

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

510(k) Number (if known): K002018

Device Name: NDO Surgical, Inc. Overtube

Indications For Use:

The NDO Surgical, Inc. Overtube is indicated for endoscopic use when repeated endoscopic intubation is anticipated.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002018

AUG 1 7 2000

K002018

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Mansfield, MA 02048

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ndo surgical, inc.

510K Summary

1. Sponsor Name

   Sponsor/Manufacturer:
   NDO Surgical, Inc.
   125 High Street, Suite #7
   Mansfield, MA 02048
   Telephone: 877-337-8887
   Contact Individual: Jeff Cerier

2. Device Name

   NDO Surgical, Inc. Overtube

3. Identification of Predicate or Legally Marketed Device

   C. R. Bard Endoscopic Overtube K973500, K942044

4. Device Description

   The NDO Surgical, Inc. Overtube is an extruded, flexible, polyvinyl chloride tube, reinforced with stainless steel wire braiding. The stainless steel reinforcing is fully encapsulated in the PVC tube. The proximal end of the Overtube has a polyurethane flange that is bonded to the tube.

   The NDO Surgical, Inc. Overtube is inserted through the patient's mouth into the esophagus following standard medical procedures. Once in place, the NDO Surgical, Inc. Overtube is used as a channel for passage of an endoscope and/or endoscopic instruments into the esophagus. It is designed and intended for circumstances in which repeated endoscopic intubation may be necessary.

5. Intended Use

   The NDO Surgical, Inc. Overtube is intended for use with an endoscope when repeated endoscopic intubation is anticipated.

6. Comparison of Technological Characteristics

   The NDO Surgical, Inc. Overtube is substantially equivalent to the predicate C. R. Bard Endoscopic Overtube in intended use, technological characteristics of the material compostion and processes used in its application. These characteristics support the concept of substantial equivalence.