5. 510(K) SUMMARY

1. SUBMITTER:

OCT 1 8 2007

NDO Surgical, Inc.
125 High St.
Mansfield, MA 02048
Telephone: 508-337-8881
Fax: 508-337-8882

Contact: John J. Vozella, V.P. Regulatory/Clinical/QA
Date Prepared: July 31, 2007

2. DEVICE:

Trade Name: Endoscopic Plication System; Plicator®
Common Name: Endoscope accessory
Classification Name: Endoscope and accessories
Class: II

3. PREDICATE DEVICE:

NDO Surgical Endoscopic Plication System (**K071553**)

4. DEVICE DESCRIPTION:

The NDO Surgical Endoscopic Plication System (EPS) deploys a suture-based implant in the stomach near the Gastroesophageal Junction thereby creating a full thickness plication of the gastric cardia for the treatment of Gastroesophageal Reflux Disease (GERD). The EPS consists of three procedural components: the Plicator instrument, the Plicator retractor and the Plicator implant cartridge. The implant cartridge and retractor are loaded onto the instrument and the instrument is then passed transorally into the stomach to create the plication.

Both the retractor and implant cartridge are provided as sterile, single use, disposable components of the EPS. The Plicator instrument is a non-sterile multiple use device that is subject to cleaning and high level chemical disinfection between uses. To facilitate cleaning and high level disinfection of the Plicator instrument with an Automated Endoscope Reprocessor (AER), the EPS will include a non-procedural "cleaning adapter" accessory.

5. INTENDED USE:

The NDO Endoscopic Plication System (EPS) is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

6. COMPARISON OF CHARACTERISTICS:

The proposed Endoscopic Plication System (EPS), is similar in design and materials and identical in fundamental operating principles and intended use to the predicate EPS device (K071553).

Proposed changes to the Plicator® labeling and accessories are as follows:

- EPS instructions for use have been modified to update cleaning and high level disinfection instructions to permit use of an AER for high level disinfection of the Plicator instrument.

- A scope channel cleaning adapter has been added as an EPS accessory to permit compatible attachment of the Plicator instrument to an AER for cleaning and high level disinfection purposes.

7. PERFORMANCE DATA:

Automated cleaning and disinfection simulated use testing using *Mycobacterium terrae* was performed in accordance with ASTM E 1837-96 (Reapproved 2002) - Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Decices (Simulated Use Test) and demonstrated that cleaning and high level disinfection of the Plicator instrument was achievable using CIDEX in a Custom Ultrasonics System 83 Plus™ Endoscope Washer/Disinfector.

8. CONCLUSION:

The modified Endoscopic Plication System (EPS) referenced in this submission is equivalent in technology, method of operation and intended use to the predicate (K071553) EPS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Mr. John J. Vozella
V.P. RA/Clinical/QA
NDO Surgical, Inc.
125 High Street, Suite 7
MANSFIELD MA 02048

Re: K072125
Trade/Device Name: Endoscopic Plication System; EPS; Plicator®
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: July 31, 2007
Received: August 2, 2007

Dear Mr. Vozella:

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 one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K072125

Device Name: Endoscopic Plication System; EPS; Plicator®

Indications for Use: The NDO EPS System (Plicator®) is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

Prescription Use __X___ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(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 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072125