JAN 3 1 2006

1. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K052930

Applicant Information:

Date Prepared:	January 20, 2006
Name:	NeoGuide Systems, Inc.
Address:	104 Cooper Court Los Gatos, CA 95032 Phone: 408-399-9999 Fax: 408-399-3386
Contact Person:	Michael A. Daniel
Phone Number:	Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number:	(925) 254-5187

Device Information:

Classification:	Class II
Trade Name:	NeoGuide Endoscopy System
Common Name:	Colonoscope
Classification Name:	Colonoscope, 78 FDF / 21 CFR 876.1500

Predicate Devices:

The NeoGuide Endoscopy System is substantially equivalent in intended use and method of operation to a combination of the following predicate devices:

K001241 – Olympus Optical Co, Ltd. EVIS EXERA Colonovideoscope
K961563 – Pentax Precision Instrument Corporation EC3840TL, Video Colonoscope
K032688 – Sightline, Colonosight, Video Colonoscope
K033954 – USGI Shape Locking Endoscopic Overtube

Device Description:

The NeoGuide Endoscopy System has many features in common with currently marketed colonoscopes. The colonoscope is manually inserted and withdrawn by the physician, who manually steers and controls it using up/down and left/right steering control knobs on a handle. The colonoscope distal tip is equipped with a CCD camera and fiber optic illumination bundles for procedural illumination. A standard tool channel is incorporated

for therapeutic procedures, as well as valves to control insuflation air, water irrigation, and suction.

The NeoGuide Colonoscope differs from currently marketed colonoscopes in that it incorporates fifteen active electro-mechanically controlled segments designed to allow the shape of the insertion tube to conform to the path defined by the physician as the colonoscope tip is manually steered through the colon lumen. The active segments are similar to conventional colonoscope steerable tips, as they each employ four control cables to articulate in the up/down and left/right directions. In order to determine the path selected by the physician during a procedure, the NeoGuide endoscopy system incorporates transducers that measure the angle of articulation of the steerable tip and the depth of insertion of the colonoscope into the patient. Software is required to create an anatomical map and interpret, monitor, and control the insertion tube segments.

Intended Use:

The NeoGuide Endoscopy System is intended to provide visualization and diagnostic / therapeutic access to the adult lower gastrointestinal tract (including, but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery.

Comparison to Predicate Device(s):

The NeoGuide Colonoscope is very similar to the predicates listed, including indications for use, patient contacting materials, and physician interface. It features a mechanically actuated tip using a conventional pull wire system which is used to steer the device with a handle essentially identical to the Olympus and Pentax predicates. The NeoGuide Endoscopy System is designed for use in the same manner as existing colonoscopes. However, the steerable distal tip section is replicated multiple times down the length of the insertion tube allowing mechanical control of the insertion tube shape and reproduction of the directional path established by the physician.

Summary:

Based upon the intended use, descriptive information, and performance evaluation provided in this pre-market notification, including *in vitro* bench, *in vivo* animal and clinical study, the NeoGuide Endoscopy System has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Mr. Michael A. Daniel
Regulatory and Clinical Affairs
NeoGuide Systems, Inc.
104 Cooper Court
LOS GATOS CA 95032

RE: K052930
Trade/Device Name: NeoGuide Navigator Endoscopy System and Accessories
Regulation Number: 21 CFR § 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: December 22, 2005
Received: December 23, 2005

Dear Mr. Daniel:

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 (Premarket Approval), 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 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" (21 CFR 807.97). 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) 443-6597 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

Indications for Use

510(k) Number (if known): _K052930

Device Name: **NeoGuide Endoscopy System and Accessories**

Indications for Use:

The NeoGuide Endoscopy System is intended to provide visualization and diagnostic / therapeutic access to the adult lower gastrointestinal tract (including, but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery.

Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

Sign-Off

on of Reproductive, Abdominal, and

ological Devices

0(k) Number K 052930