AUG 15 2006

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

NAVIAID™ BGE DEVICE

510(k) Number K060923

Applicant's Name:

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Name of the device:

NaviAid™ BGE device

Trade or proprietary name, if applicable:

NaviAid™ BGE device

Common or usual name:

Balloon Guided Endoscope Accessory Device or Balloon Guided Endoscopy Accessory Device

Establishment Registration No.:

Establishment registration form (Form FDA 2891) has been submitted but no registration number has been assigned yet.

Classification Name:

Gastrointestinal Tubes (and accessories)

Classification:

FDA has classified Double Balloon Endoscope devices as a Class II medical device, with product code KNT and 21 CFR classification code 876.1500. Review by the Gastroenterology/Urology Devices Panel.

Predicate Device:

The NaviAid™ BGE device is substantially equivalent to the Double Balloon Enteroscopy System (manufactured by Fujinon Inc. and the subject of 510(k) document no. K040048). A comparison table and detailed discussion are presented in Section 12 of this application.

Device Description:

The NaviAid™ BGE affords deep access into the small intestine, while maintaining all the advantages of an endoscopic procedure, such as back-and-forth navigation, stopping propagation if needed, real-time operation, video imaging, working channel including biopsy and treatment.

The NaviAid™ Balloon Guided Endoscopy (BGE) system comprises an accessory kit containing the disposable balloon system and an air supply control unit for inflating and deflating the balloon system. The role of the Balloon Guided Endoscopy (BGE) disposable accessory kit is to facilitate advancement of a standard endoscope deeper into the small intestine. The NaviAid™ BGE system "upgrades" standard endoscopes to a double balloon endoscopy system. The NaviAid™ BGE accessory kit includes two balloons – the Guiding Balloon for Small Intestine ("GBS") and the Stabilizing Balloon ("SB"). Both balloons are inflated by ambient air. The Air Supply Unit ("ASU") operates and controls the inflation and deflation of the two balloons through two foot-pedals. Each balloon is connected to a dedicated tube that runs along the endoscope, and is connected at its proximal (user) end to the ASU. The balloon tubes are attached to the endoscope with clips and silicon bands.

The NaviAid™ BGE accessory kit is mounted (deflated) on the tip of the endoscope, and is inserted with the endoscope into the gastrointestinal tract of the patient. The SB is the proximal balloon that is used to anchor the endoscope (near its tip) to the intestinal wall. The GBS is the distal balloon that can be advanced ahead of the endoscope tip or pulled back through pushing/pulling action on the GBS inflation tube at its proximal side, outside the patient body. When the GBS balloon is advanced and then inflated, it functions as a distal anchor, to which the endoscope tip (now with a deflated balloon) is advanced, and the GBS inflation tube serves as a "guidewire" that leads the endoscope as it is pushed towards the anchoring GBS balloon. The sequence of inflation and deflation of the balloons enables "pleating the small intestine on to the endoscope" or forming a rail on which the endoscope can be guided and advanced towards the GBS anchoring location.

The balloons and tubes do not compromise the endoscope's flexibility, although its field of view may be reduced by up to 8%. Additionally, the balloons do not significantly compromise the maneuverability of the endoscope's tip and do not limit the usage of any standard endoscopy tools, such as biopsy forceps, snare, needle etc.

The NaviAid™ BGE accessory kit is disposable and intended for single use, while the ASU is re-usable.

Intended Use / Indication for Use:

The NaviAid™ BGE device is an accessory to an endoscope and is intended to ensure complete positioning of a standard endoscope in the small intestine (i.e., an endoscope that is 10-13 mm in diameter and is used for standard intestinal endoscopic visualization).

Comparison of Technological Characteristics with the predicate device:

The BGE device is similar to the Fujinon Double Balloon Endoscopy System regarding intended use and regarding the technological characteristics of the device.

Both the NaviAid™ BGE device and the Fujinon System are intended to facilitate penetration of standard endoscopes deep into the small intestine, while maintaining all the advantages of an endoscopic procedure, such as back-and-forth navigation, stopping propagation if needed, real-time operation, video imaging, working channel including biopsy and treatment. Both devices are based on the same basic principles of operation, that is, utilization of specialized double balloons based on an endoscopy system, that are alternately inflated and deflated in order to progress the endoscope and ensure complete positioning of the endoscope in the small intestine.

The devices both include the same basic components for achieving complete positioning of the endoscope in the small intestine, including an air supply unit & control pump and a double balloon system for advancing the endoscope. Although, in the Fujinon system one balloon is an integral part of the endoscope device (though it is disposable and replaced

after every procedure) and the second balloon is positioned on an overtube, whereas, in the NaviAid™ BGE device both balloons are separate components not connected to the endoscope, thus enabling use of the device with any standard endoscope.

The balloon pressure specifications are also similar, as are the outer diameter of the fully inflated portion of the balloon. The working length of the systems is slightly different; the working length of the Fujinon System is 1,350 mm, whereas the working length of the NaviAid™ BGE device depends on the endoscope device and is typically 2,200 mm. Both devices are supplied non-sterile, for single use only.

The patient contact materials and accessories provided with the device are different. The Fujinon system is supplied with endoscopy accessories such as a light source, biopsy forceps, etc., whereas the NaviAid™ BGE device is obviously not supplied with these accessories, as such accessories are supplied with the user supplied endoscope. Similar accessories include a foot pedal for additional control of the inflation/deflation sequencing. The NaviAid™ BGE device is also supplied with additional accessories to facilitate connecting the BGE disposable balloon system to the endoscope device (e.g. silicone bands and o-ring).

Both the NaviAid™ BGE device and the Fujinon System comply with the electrical and mechanical safety testing requirements and the electromagnetic compatibility testing requirements for electronic medical devices.

Non-Clinical Performance Data

The following performance tests were conducted on the NaviAid™ BGE device:

1. Electrical & Mechanical Safety Testing (IEC 60601-1)
2. Electromagnetic Compatibility Testing (IEC 60601-1-2)
3. Software Validation (IEC 60601-1-4 & FDA Guidelines)
4. Biocompatibility Testing (ISO 10993)
5. ASU Test
6. Bond Strength Test
7. Air Leakage Test
8. Balloon Burst Pressure Test
9. GBS Inflation Tube & Bending Radius Test
10. Endoscope Flexibility & Insertion Test
11. Components Degradation Test
12. Endoscope Diameter Test
13. GBS Inflation/Deflation Cycle Test
14. ASU Connections
15. Disposables Mounting Testing
16. In-Vitro Validation Test
17. Packaging Validation

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The non-clinical tests demonstrated that the NaviAid™ BGE device meets its design and performance specifications. Furthermore, the tests showed that the NaviAid™ BGE device is easy to use and user friendly and does not cause damage to the intestine.

The NaviAid™ BGE device may be safely and effectively used in Balloon Guided Endoscopy procedures in order to reach depths of the intestine that may not otherwise be accessible with a standard endoscope device.

Substantial Equivalence:

In summary, the intended use and principle of operation of the NaviAid™ BGE device and the Fujinon Double Balloon Endoscopy System are the same. Furthermore, the basic technological characteristics of the devices, including basic components, design, specifications and safety requirements, are similar. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the NaviAid™ BGE device is substantially equivalent to the Fujinon Double Balloon Endoscopy System.

Performance Standards:

The NaviAid™ BGE device complies with the voluntary recognized standards:

1. Electrical & Mechanical Safety Testing (IEC 60601-1)
2. Electromagnetic Compatibility Testing (IEC 60601-1-2)
3. Software Validation (IEC 60601-1-4 & FDA Guidelines)
4. Biocompatibility Testing (ISO 10993)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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AUG 15 2006

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% Ms. Ahava Stein
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20 Hata'as St., 44425 Kfar Saba
ISRAEL

Re: K060923
Trade/Device Name: NaviAid™ BGE Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDA and KOG
Dated: August 4, 2006
Received: August 8, 2006

Dear Ms. Stein:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060923

Device Name: NaviAid™ BGE Device

Indications for use: The NaviAid™ BGE device is an accessory to an endoscope and is intended to ensure complete positioning of a standard endoscope in the small intestine (i.e., an endoscope that is 10-13 mm in diameter and is used for standard intestinal endoscopic visualization).

Prescription Use √ OR Over-The-Counter Use___
(Per 21 C.F.R. 801 Subpart D) **(Optional Format 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
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060923