SECTION 5 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

NaviAid™ BGC device

DEC 30 2010

510(k) Number K 102616

pg 1 of 7

Applicant's Name:

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Name of the device:

NaviAid™ BGC device

Trade or proprietary name, if applicable:

NaviAid™ BGC device

Common or usual name:

Balloon Guided Colonoscopy Device

Establishment Registration No.:

3005261802

Classification Name:

Endoscope and accessories

Classification:

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

Predicate Device:

The NaviAid™ BGC device is substantially equivalent to the NaviAid™ ICVI device (manufactured by Smart Medical Systems Ltd. and the subject of 510(k) document no. K101191) and the Double Balloon Colonoscope (manufactured by Fujinon and the subject of 510(k) document no. K090116). A comparison table and detailed discussion are presented in Section 12 of this application.

Device Description:

The NaviAid™ BGC Disposable is an on-demand disposable that is inserted through the instrument channel of the endoscope in order to ensure positioning of a standard endoscope during endoscopy of the large or small intestine (standard endoscope - i.e., an endoscope that has an instrument channel that is at least 3.7mm diameter and is used for standard endoscopic visualization). The NaviAid™ BGC system comprises a disposable balloon system and an Air Supply Unit for inflating and deflating the balloon system. The role of the BGC disposable is to facilitate advancement of a standard endoscope into the large and/or small intestine. The NaviAid™ BGC Disposable includes the BGC Balloon and the BGC inflation tube. The balloon is inflated by ambient air. The Air Supply Unit ("ASU") operates and controls the inflation and deflation of the balloon through a foot-pedal. The balloon is connected to a dedicated inflation tube that runs inside the instrument channel of the endoscope, and is connected at its proximal (user) end to the ASU. The BGC balloon can be advanced ahead of the endoscope tip or pulled back by pushing/pulling action on the BGC inflation tube at its proximal side, outside the patient's body. When the BGC balloon is advanced and then inflated, it functions as a distal anchor, to which the endoscope tip is advanced, and the BGC inflation tube serves

as a "guide wire" that leads the endoscope as it is pushed towards the anchoring BGC balloon.

The balloon and tube negligibly compromise the endoscope's flexibility, or its field of view. Additionally, the BGC disposable negligibly compromise the maneuverability of the endoscope's tip and does not limit the usage of any standard endoscopy tools, such as biopsy forceps, snare, needle etc. The BGC disposable can be pulled back at any time during the procedure in order to allow use of therapy tools.
The NaviAid™ BGC disposable is intended for single use, while the ASU is re-usable.

Intended Use / Indication for Use:
The NaviAid™ BGC device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope during endoscopy of the small and large intestine (standard endoscope-i.e., an endoscope that has an instrument channel that is at least 3.7mm diameter and is used for standard endoscopic visualization).

Comparison of Technological Characteristics with the predicate device:
a. Comparison between the NaviAid™ BGC device and the NaviAid™ ICVI device

The NaviAid™ BGC device is similar to the NaviAid™ ICVI device regarding the intended use, technological characteristics, principle of operation, specifications, materials and safety requirements of the device.
Both the NaviAid™ BGC device and the NaviAid™ ICVI device are intended to ensure positioning of standard endoscopes in the 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, instrument channel including biopsy and treatment. During both the NaviAid™ BGC procedure and the NaviAid™ ICVI procedure the disposables can be removed from the instrument channel of the endoscope and a therapy tool may inserted instead. The NaviAid™ BGC device is intended for the large and small intestine while the NaviAid™ ICVI device is intended for the small intestine.
The NaviAid™ BGC includes a single balloon; similarly to the NaviAid™ ICVI balloon. The balloon traverses ahead of the endoscope through the endoscope's instrument

channel, thus it can be applied on demand and there is no need for a pre-procedure preparation of the device. The utilization of the BGC balloon and the ICVI balloon is the same and their characteristics are similar. They are both designed to anchor the intestine at similar pressure and be maneuvered manually in a similar form.

Both the NaviAid™ BGC and the NaviAid™ ICVI utilizes specialized single balloon system used with standard endoscopy system (standard endoscope i.e. an endoscope that is used for the intestinal visualization and has an instrument channel that is at least 3.7mm diameter).

Both the ICVI balloon BGC Balloon can be advanced ahead of the endoscope tip or pulled back by pushing/pulling action on the inflation tube at its proximal side, outside the patient's body. When the balloon is advanced and then inflated, it functions as a distal anchor, towards which the endoscope tip is advanced, and the inflation tube serves as a "guide wire" that leads the endoscope as it is pushed towards the anchoring balloon.

Both the BGC Disposable and the ICVI Disposable are supplied non-sterile, for single use only and is supplied in a Tyvek pouch.

All patient contact materials comply with biocompatibility testing.

The NaviAid™ ASU is identical in both the BGC device and the NaviAid™ ICVI device and complies with the electrical and mechanical safety testing requirements and the electromagnetic compatibility testing requirements for electronic medical devices.

b. Comparison between the NaviAid™ BGC device and the Double Balloon Colonoscope

The NaviAid™ BGC device is similar to the Double Balloon Colonoscope regarding the intended use, technological characteristics, principle of operation and safety requirements.

Both the NaviAid™ BGC device and the Double Balloon Colonoscope are intended to facilitate positioning of an endoscope in the 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, instrument channel including biopsy and treatment. During the NaviAid™ BGC procedure the NaviAid™ BGC

disposable can be removed from the instrument channel of the endoscope and a therapy tool may inserted instead. The Double Balloon Colonoscope's instrument channel may be used for the insertion of a therapy tool during the procedure.

Both devices include similar components for achieving positioning of the endoscope in the intestine, including an Air Supply Unit / Air Pump and a balloon system for advancing the endoscope. In both devices the balloon system utilizes an endoscope and is controlled by the balloon pump. The pump controls inflation and deflation of the balloon system.

The Fujinon Double Balloon Colonoscope System features two balloons, one attached to the distal end of the endoscope and the other attached to a tube sliding over the Colonoscope (an over-tube). The balloon and over-tube are mounted on the endoscope prior to the Double Balloon Colonoscopy procedure. When inflated with air, the balloons anchor onto the intestine and facilitate the advancement of the endoscope deeper into the intestine. The NaviAid ™ BGC device features a single balloon system. The balloon traverses ahead of the endoscope through the endoscope's instrument channel, thus it can be applied on demand and there is no need for a pre-procedure mounting and preparation of the device. Similarly to the Double Balloon Colonoscope, when inflated with air, the NaviAid™ BGC balloon anchors onto the intestine and facilitates advancement of the endoscope deeper into the intestine.

The NaviAid™ BGC utilizes specialized single balloon used with standard endoscopy system (standard endoscope-i.e. an endoscope that is used for intestinal visualization and has an instrument channel that is at least 3.7mm diameter). The balloon can be moved back and forth ahead of the endoscope tip by pushing/pulling action on the inflation tube at its proximal side, outside the patient's body. When the balloon is advanced and then inflated, it functions as a distal anchor, towards which the endoscope tip is advanced, and the inflation tube serves as a "guide wire" that leads the endoscope as it is pushed towards the anchoring balloon.

The air supply unit and control pump are much the same with similar dimensions, weight, electrical input and indicators.

The BGC Disposable is supplied non-sterile, for single use only and is supplied in a Tyvek pouch. The Fujinon Double Balloon Colonoscope System disposable components are supplied sterile.

All patient contact materials comply with biocompatibility testing

Both the NaviAid™ BGC device and the Fujinon Double Balloon Colonoscope 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 performance tests include testing of the NaviAid™ BGC Device.

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

1. BGC Handle and Instrument Channel Compatibility (Doc. No. TP310001)
2. BGC Air Leakage (Doc. No. TP310003)
3. BGC Bending Radius (Doc. No. TP310005)
4. Endoscope Flexibility (Doc. No. TP310006)
5. BGC Assembly Degradation Test (Doc. No. TP310007)
6. BGC Inflation/Deflation Test (Doc. No. TP310009)
7. BGC In-Vitro Validation Test (Doc. No. TP310014)
8. Packaging Validation (ISO 111607/Doc. No. TP310015)
9. BGC Balloon (Doc. No. TP310019)
10. Component Bond Strength (Doc. No. TP320034)
11. BGC Balloon Cover (Doc. No. TP310077)

Clinical Performance Data

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

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

The NaviAid™ BGC device may be safely and effectively used in procedures in order to ensure positioning of a standard endoscope into the small and large intestine.

Clinical Performance Data

Not Applicable

Substantial Equivalence:

In summary, the NaviAid™ BGC Device is a similar to both the NaviAid™ ICVI device and the Double Balloon Colonoscope in intended use, basic technology, principle of operation and safety requirements. The minor differences in specifications do not raise new questions of safety and effectiveness. Consequently, the NaviAid™ BGC device is substantially equivalent to the NaviAid™ ICVI Device and to Double Balloon Colonoscope and no new questions of safety and effectiveness are raised.

Performance Standards:

The NaviAid™ BGC 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)

Note: Though the Air Supply Unit (ASU) is identical for both the NaviAid™ BGC and the NaviAid™ ICVI, and performance tests relating to standards 1-2 listed above are described is K101191 of the NaviAid™ ICVI , for the reviewer's convenience the performance tests relating to standards 1-2 listed above are described in detail again in section 17 of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Ms. Adva Yoselzon
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SMART® Medical Systems Ltd.
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DEC 30 2010

Re: K102616
Trade/Device Name: NaviAid™ BGC Device
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: December 2, 2010
Received: December 8, 2010

Dear Ms. Yoselzon:

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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102616

Device Name: NaviAid™ BGC Device

Indications for use:

The NaviAid™ BGC device is an accessory to an endoscope and is intended to ensure positioning of a standard endoscope during endoscopy of the small and large intestine (standard endoscope-i.e., an endoscope that has an instrument channel that is at least 3.7mm diameter and is used for standard 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102616