



Food and Drug Administration
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October 26, 2015

Beacon Surgical Incorporated
Mr. Allan Alward
Vice President, Research and Development
145 Palisade Street
Dobbs Ferry, New York 10522

Re: K151489
Trade/Device Name: Retrieval Bag System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 17, 2015
Received: September 23, 2015

Dear Mr. Alward:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Beacon Surgical, Inc.

Indications for Use

510(k) Number: K151489

Device Name: Beacon Bag Specimen Retrieval Bag

Indications for Use:

The Beacon Bag Specimen Retrieval Bag System consists of a family of impervious bags that are sterile, single use, disposable devices having applications as a receptacle for the safe encapture and removal of tissue specimens, organs and calculi during laparoscopic surgical procedures that can be used alone or with a dedicated introducer system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Beacon Surgical, Inc.

510(k) Summary
(as specified by 21 CFR 807.92)
Prepared September 17, 2015

Device Name: Beacon Bag Specimen Retrieval Bag

Intended Use:

The Beacon Bag Specimen Retrieval Bag System consists of a family of impervious bags that are sterile, single use, disposable devices having applications as a receptacle for the safe encapture and removal of tissue specimens, organs and calculi during laparoscopic surgical procedures that can be used alone or with a dedicated introducer system.

Establishment Registration Number: 3011666923

Regulatory Contact

Allan Alward
145 Palisade Street
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914-479-5108

Sponsor/Manufacturer

Beacon Surgical Inc.
145 Palisade Street
Dobbs Ferry, NY 10522
Tel: 914.591.8400

Device Trade or Proprietary Names:

The device trade names are: Beacon Bag Specimen Retrieval Bag

Device Common, Usual or Classification Names:

Laparoscopic Instruments, Specimen bag.

Classification Panel:

Classification of this device falls under the responsibility of the General and Plastic Surgery Panel.

Class:

Class 2 device under the following product codes/regulations:

- GCJ, 21 CFR 876.1500, Endoscope Accessories

Applicable Standards:

Compliance with Section 514 of the Food, Drug and Cosmetic Act

None. Section 514 has not established performance standards for this device.

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Device Description:

Summary of the function of the device and its major components:

The Beacon Bag Specimen Retrieval Bags are comprised of an introducer tube with a blunt tip, flexible fiber reinforced plastic bag with a large, easily accessible opening. With the blunt tip the instruments can be introduced percutaneously to the intended surgical site directly through an opening in the abdomen or through a conduit cannula/trocar for sizes under 16 mm, after which the working portion of the instrument can be deployed. The deployment systems consists of either a push/pull rod with thumb ring (similar to a syringe), finger ring handle, or a back handle and a push button with an internal push rod, all instruments have a blunt tip nose used for direct insertion into the abdomen. In the fully deployed condition, the bag opening is maintained in an open position by metallic rings. A suture with a slipknot and perforations of the bag under where the bag is attached to the rings facilitates closure of the specimen bag after the specimen has been collected into the bag, the suture or purse string is connected to an external part (string ring).. The specimen bag has a series of perforations around the perimeter so when the purse string suture is pulled and the bag starts to cinch and separates from the metallic rings, this is accomplished by pulling the external string ring.

The larger sized Beacon Bag Specimen Retrieval Bags, 16mm and 20mm come with a side access tube which allows for additional access into the bag without compromising the integrity of the bag opening to visualize the specimen inside the bag. This is accomplished by using a 5 mm or less sized instruments and scopes to be introduced directly into the bag for additional visualization and manipulation where required.

Patient Contact Materials:

The device is composed of biocompatible materials including the patient contact components that have been used in medical devices for many years.

Cleaning, Disinfection, Sterilization and Pyrogenicity:

The Beacon Bag Specimen Retrieval Bags are a family of sterile disposable single patient use devices packaged in a sterile barrier pouch which will be Ethylene oxide (ETO) sterilized.

The disposable Beacon Bag Specimen Retrieval Bag will be sterilized using Ethylene oxide (ETO) sterilized, validated in production to a SAL of 10^{-6} per ISO 11135:2007.

510(k) Summary of Safety and Effectiveness:

The Beacon Bag Specimen Retrieval Bag utilizes technologies that are currently found in legally marketed predicate devices. Based upon testing and comparison with the predicate devices, the Beacon Surgical Specimen retrieval bag system presents no additional adverse indications or results. We have found that the Beacon Bag Specimen Retrieval Bag system does not present any new risks to the patient and that it is safe and performs within its design specifications. Therefore we believe that it is substantially equivalent to the predicate device and other technologies cleared by the FDA.

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Technological Characteristics:

Beacon Surgical, Inc. believes that the subject device is substantially equivalent to other devices that have previously received FDA 510(k) clearance including the predicate devices.

Predicate Device:

The following devices have been identified as predicate devices:

- Espiner Tissue Retrieval System (K111845).
- Anchor Espiner Tissue Retrieval System (K982073).

Predicate Device Comparison:

The Beacon Bag Specimen Retrieval Bag's are, in principal and function, identical to existing technologies. A variety of specimen retrieval bags are already widely manufactured and used in surgical procedures which share many similarities to the Beacon Bag Specimen Retrieval Bag. The predicate device's bags are of the same materials and processes and produced by the same manufacturer which has approval under 510(k) (K111845) for Espiner and (K982073) for Anchor. Espiner is the original manufacturer of the bag family which will be the bag for the Beacon bag specimen retrieval system.

Discussion on Comparison:

The main difference between the Beacon Bag Specimen Retrieval Bags is that the Espiner Medical, K111845 and the Anchor Products K982073 are designed for introduction and use through appropriately sized trocars/cannulas. Whereas the Beacon Bag Specimen Retrieval system can be used without the need for an insertion conduit or cannula, as the product comes with a blunt tip for entering into the body cavity through an entrance wound. The larger sized units have an additional access tube similar to the Espiner larger bag which allows for additional instruments or laparoscope to be used. All three units share the identical bag material and manufacturing processes. The other differences are the deployment system where the Espiner bag has to be loaded into a unit to be deployed, the Beacon Specimen Bag system houses the bag assembly internally and will deploy similar to present systems currently on the market and release from the rings when the bag is cinched through the perforations around the ring channel. The main difference between the Beacon Bag Specimen Retrieval Bags is that the Espiner Medical, K111845, and the Anchor Products K982073 are designed for introduction and use through appropriately sized trocars/cannulas. Whereas the Beacon Bag Specimen Retrieval system can be used without the need for an insertion conduit or cannula, as the product comes with a blunt tip for entering into the body cavity through an entrance wound. The larger sized units have an additional access tube similar to the Espiner larger bag for additional access by another instrument or laparoscope into the bag. All three units utilize the exact same material in the bags, and the method of construction of the Beacon bags, Esacs and the E-sleeves are identical. The differences between the Beacon Bags and the Espiner bags Standard, Super, Master and Eco are only in the methods of deployment, and release from the instrument. The other differences are the deployment system where the Espiner bag has to be loaded into a unit to be deployed, the Beacon Specimen Bag system houses the bag assembly internally and will deploy similar to present systems currently on the market. The beacon bags are all attached to a ring and are inside a tube that when

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deployed will unfurl. Once unfurled the bags can be cinched and have perforations around the bag so that when the bag is cinched closed the perforations allow the bag to separate from the rings internally.

Predicate Comparison Chart:

Characteristic	<u>Beacon Surgical</u>	<u>Espiner</u>	<u>Anchor Products Company.</u>
	Beacon Bag Specimen Retrieval Bag	Espiner Tissue Retrieval System	Anchor Espiner Tissue Retrieval System
510(k)	K151489	K111845	K982073
Use	The Beacon Bag Specimen Retrieval Bag System consists of a family of impervious bags that are sterile, single use, disposable devices having applications as a receptacle for the safe encapture and removal of tissue specimens, organs, and calculi during laparoscopic surgical procedures that can be used alone or with a dedicated introducer system.	The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use devices that can be used alone or with a dedicated introducer system for the encapture and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery.	The Anchor Espiner Tissue Retrieval system is a sterile disposable pouch that can be used with a dedicated introducer system for the encapture and removal of an organ, tissue, or fluid from the body cavity during laparoscopic surgery.
Outer diameter	7.5mm, 10 mm, 12.5mm, 16 mm, 20mm	10 mm, 12 mm and 15mm	10 mm, 12mm and 15mm
Device length	Approximately 30 cm	Approximately 30 cm	Approximately 30 cm
Bag Volume	RBS-7.5 mm, 40 ml RBS- 10 mm, 195 ml RBS-16mm, 1507 ml	EMP-70 INS, 60 ml EMP-200, 200 ml EMP 160 WG, 1500 ml	
Material Composition	Medical Grade type 301 Stainless Steel and Medical grade polymers.	Equivalent	Equivalent
Sterilization	ETO	ETO	Equivalent
Bag/Pouch Material	Nylon laminate polyurethane	Nylon laminate polyurethane	Nylon laminate polyurethane

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Table of Contents:

A table of content is included at the beginning of this submission. The pages referred to in the contents correspond to the sequentially numbered pages of this premarket notification.

Truthful and Accurate Statement:

A “truthful and accurate” statement regarding all information provided in this premarket notification is present on page.

Confidentiality:

Beacon Surgical, Inc. considers certain information in this premarket notification to be confidential business information, and has taken measures to protect the release of this information. Beacon Surgical, Inc. requests the FDA respect the confidentiality of this information to the extent possible under law. We expect the FDA will consult with Beacon Surgical, Inc. prior to the release of any information in this premarket notification (outside the 510(k) summary) for any reason, including requests under the Freedom of Information Act.

Performance Data [21 CFR 807.92(b) (1)]:

The devices components being utilized from the predicate device K111845 have been subjected to and passed a variety of bench tests along with sterilization and aging. Additionally, the critical functions of the device have been tested for verification under protocol's BS-0101 and BS-0102 and have met the stated requirements. All of the components used in the manufacturing of the device are composed of biocompatible materials with a history of usage in the medical device industry. The protocols are in Annex 6

Conclusion [21 CFR 807.92(b) (3)]:

We believe the differences are minimal and conclude that the subject device is as safe and effective as the predicate devices.