DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 7, 2016

Beacon Surgical, Inc.
Mr. Allan Alward
Vice President Research and Development
145 Palisade Street, Suite 101
Dobbs Ferry, New York 10522

Re: K153542
Trade/Device Name: Pelican Sling Retractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 2, 2016
Received: August 4, 2016

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 Part 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 Parts 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,

Christopher J. Ronk -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: Not Assigned

Device Name: Pelican Sling Retractor

Indications for Use:

The Pelican Sling Retractors have applications in a variety of gynecologic, general, urologic, thoracic, colorectal, laparoscopic and endoscopic procedures for the temporary retracting of internal structures such as organs or tissue.

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)
Revised September 1, 2016

Device Name: Pelican Sling Retractor

Intended Use:

The Pelican Sling Retractors have applications in a variety of gynecologic, general, urologic, thoracic, colorectal, laparoscopic and endoscopic procedures for the temporary retracting of internal structures such as organs or tissue.

No Previous NSE Decision:

This device has not been the subject of a previous NSE decision nor has there been other submissions or communication to the FDA regarding this device.

Establishment Registration Number:

Regulatory Contact
Allan Alward
145 Palisade Street, Suite 101
Dobbs Ferry, NY 10522
914-479-5108

Sponsor/Manufacturer
Beacon Surgical LLC.
145 Palisade Street, Suite 101
Dobbs Ferry, NY 10522
Tel: 914-479-5108

Device Trade or Proprietary Names:
The device trade names are: Pelican Sling Retractor.

Device Common, Usual or Classification Names:
Laparoscopic Retractor, Tissue Retractor.

Review 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

Compliance with Section 514 of the Food, Drug and Cosmetic Act
None, Section 514 has not established performance standards for this device.

Device Description:

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

The Pelican Sling Retractors are comprised of a tube with a blunt tip, a flexible polymer mesh, or a flexible polymer film used for the sling, for use during retraction of tissue. The deployment system consists of a dial that when turned deploys or closes the sling portion of the instrument. All sizes have a Blunt tip for ease of insertion, and to protect the end of the instrument during insertion. All Pelican Sling Retractors have a removable sheath that protects the sling portion of the instrument. When the instrument is fully deployed, the sling opening is maintained in an open position by a tube on one side and a metallic band on the other. The size of the sling can be varied by the amount of rotation of the dial during deployment or closing. The smallest instrument has a straight shaft and can be inserted with or without a trocar/cannula used as a conduit for insertion. The larger sizes have both a straight and curved shaft. The straight shaft can be used with the aid of a correctly sized trocar/cannula, whereas the curved can only be used with a correctly sized flexible trocar/cannula.

Either unit can be used without a trocar/cannula the only requirement is an opening into the abdomen. The Pelican Sling Retractor instruments have variations in the diameter of the shaft and the size of the Sling portion. The smallest size has a 4.5 mm diameter shaft and a sling that is approximately 9 cm x 6 cm, and can be used through a 5 mm trocar/cannula. The larger size devices have straight and curved shafts with a diameter of 6.5 mm for both. Both instruments slings when fully deployed open to approximately 15 cm x 9 cm. The large straight instrument can be inserted through an appropriately sized normal fixed trocar whereas the curved when used with a trocar can only be used with an appropriately sized flexible trocar.

Cleaning, Disinfection, Sterilization:

The Pelican Sling Retractors are a family of sterile disposable, single patient use devices packaged in a sterile barrier pouch which will be sterilized using gamma radiation, validated in production to a SAL of 10^{-6} per ISO 11137, Method 1, in order to reduce gamma exposure/aging. When applicable, the VDmax provisions of 11137 will be used to substantiate the standard 25-to-40 kGy dose.

Predicate Device:

The following devices have been identified as a predicate device:

- The A-Lap™ Set, the A-Lap™ Retractor and EZaxess (EZ Surgical) K082291.
- Covidien: Auto suture Endo paddle retractor (Auto suture); 510(k) exempt.

Predicate Device Comparison:

The Pelican Sling Retractors are in principal and function, identical to existing technologies. A variety of fabric and or polymeric type retractors are already manufactured and used in surgical procedures and share many similarities with the Pelican Sling Retractors.

A comparison is presented in the table below:

Characteristic	**Beacon Surgical**	**EZ Surgical Inc.**	**Covidien**
	Pelican Sling Retractors	A-Lap™ Set, the A-Lap™ Retractor, and the EZaxess	Endo paddle retractor
510(k)	K153542	K082291	Not Assigned , Exempt
Device classification	Class 2	Class 2	Class 1
Indications for use.	The Pelican Sling Retractors have applications in a variety of gynecologic, general, urologic, thoracic, colorectal, laparoscopic, and endoscopic procedures for the temporary retracting of internal structures such as organs or tissue.	The EZaxess is intended for use in creating and maintaining a port of entry in gynecologic, general, urologic and thoracic procedures. The A-Lap™ retractor has application for use in the creation and maintenance of an operative cavity such as the gynecologic, general, urologic and thoracic procedures. The device may be used in procedures requiring temporary retracting of tissue. The A-Lap™ set has application for use in the creation and maintenance of an operative cavity such as the gynecologic, general, urologic and thoracic procedures. The set may be used in procedures to create and maintain a port of entry and for temporary retracting of tissue.	The instrument has application in a variety of gynecologic, general, urologic, thoracic, colorectal and other endoscopic procedures for retracting internal structures, e.g., the bowel, stomach, or liver.
Outer shaft diameter	Approximately 4.5 mm and 6.5 mm	Approximately 6.5 mm	Approximately 12mm
Retractor size	Approximately 9 cm x 6 cm and 15 cm x 9 cm	12 cm X 12 cm	Approximately 9 cm x 9 cm
Device length	Approximately 30 cm	Approximately 30 cm	Approximately 30 cm
Material Composition	Medical Grade Stainless Steels and medical grade polymers.	Medical Grade Stainless Steels and medical grade polymers.	Medical Grade Stainless Steels and medical grade polymers.
Sterilization	Gamma, sterile single use disposable	Unknown, sterile single use disposable	ETO, sterile single use disposable
Sling, Paddle Fabric Material	Polymer (Nylon) mesh, polyurethane sheet	Polymer (Polyester) Mesh	Polymer (Nylon) type mesh

Beacon Surgical, Inc.

Discussion on Comparison:

The main differences between the Pelican Sling Retractors and the Endo paddle (No k number), the A-Lap™ Retractor (K082291) is that the Beacon instrument can be used with or without the need for a trocar/cannula as a conduit to enter the body cavity when used laparoscopically. Whereas the Endo paddle and the A-Lap™ Retractor are designed for introduction and use through appropriately sized trocars/cannulas in order to gain access to the body cavity. The products are similar in respect to the deployment of the retractor system (sling, paddle, and basket), and the materials used in the construction of the devices are similar.

To deploy the Pelican sling retractors a dial is rotated in the handle portion of the instrument which allows the sling to be extended or retracted. The deployment of the Endo Paddle is similar where a knob is rotated that is situated at the back of the instrument to deploy and retract and the A-Lap™ Retractor is extended by manipulation of the finger grips.

One other major difference is that the Endo paddle requires the use of a larger trocar and thus creates more trauma to the body; the shaft diameter is almost twice as large as the Pelican Sling and A-Lap™ retractors which are similar in diameter.

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

The critical functions of the device have been tested both in vitro and in vivo and the data confirms the safety and effectiveness of the device and that the basic functional characteristics for ergonomics and strength, are substantially equivalent to the predicate devices cited. Device evaluation included flexibility, mechanical strength tests for the sling portion, and shaft along with the deployed size of the slings.

Biocompatibility of the Pelican Sling Retractor materials has been verified in accordance with ISO 10993-l. Biological evaluation of Medical Devices – Part 1. Materials test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) device.

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

Based on the indications for use, technological characteristics, and performance testing. We believe the Pelican Sling Retractors meet the minimum requirements that are considered adequate for intended use and is substantially equivalent in design, materials, principles of operation and indications for use and conclude that the subject device is as safe and effective as the predicate device.