



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

June 8, 2015

Slater Endoscopy, LLC
% Craig Pagan
Consultant
C2C Development, LLC
1135 W Nasa Blvd, Suite 500
Melbourne, FL 32901

Re: K150939
Trade/Device Name: Ensizor Endoscopic Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCZ
Dated: March 25, 2015
Received: April 7, 2015

Dear Craig Pagan,

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,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150939

Device Name

Slater Endoscopy Ensizor™ Endoscopic Scissors

Indications for Use (Describe)

Slater Endoscopy Ensizor™ Endoscopic Scissors are designed to cut and dissect tissue and sutures during all flexible endoscopic procedures

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(1) **Submitter's name, address, telephone number, a contact person and date summary was prepared:**

Slater Endoscopy, LLC
14000 NW 58 Ct.
Miami Lakes, FL 33014
Telephone: (305) 889-3350
Contact: John Starkey, Chief Operating Officer and Vice President Quality Assurance
Mar 25, 2015

(2) **Name(s) of device:**

<u>Proprietary/Trade Name:</u>	Ensizor™ Endoscopic Scissors
<u>Common Name:</u>	Endoscope and/or Accessories
<u>Classification Name:</u>	Endoscope and Accessories (21 CFR 876.1500)
<u>Classification Panel</u>	Gastroenterology/Urology
<u>Product Code:</u>	OCZ
<u>Regulatory Class:</u>	II

(3) **Legally Marked Predicate Device to which the submitter claims substantial equivalence:**

The Ensizor™ Endoscopic Scissor is substantially equivalent to the Ensizor™ Endoscopic Scissor (K141058) and the US Endoscopy Suture Cutter Device (K133736).

(4) **Description of device(s):**

Ensizor™ Endoscopic Scissor

- Cat # ES-26165 2.6 mm Endoscopic Scissors x 165cm working length
- Cat # ES-26235 2.6 mm Endoscopic Scissors x 235cm working length

The above referenced Endoscopic Scissors are sterile, single use, non-electrocautery devices for soft tissue dissection and the cutting of sutures during flexible endoscopic procedures. The devices are compatible with flexible endoscopes with a minimum channel diameter of 2.8 mm. The device cuts and dissects tissue and suture materials during all flexible endoscopic procedures. The device consists principally of an actuation handle and a flexible shaft body terminating in a pair of cutting scissors. The scissor blades function as standard scissors for mechanical cutting of sutures and tissue.

(5) **Statement of intended use:**

Slater Endoscopy Ensizor™ Endoscopic Scissors are designed to cut and dissect tissue and sutures during all flexible endoscopic procedures.

(6) **Comparison of Technological Characteristics to Predicate Device:**

The Ensizor™ Endoscopic Scissors have the same technological characteristics as the predicate devices as described below:

Comparison to K141058 – Ensizor™ Endoscopic Scissors

- The device design, materials, manufacturing, packaging and sterilization is exactly the same as the Ensizor™ Endoscopic Scissors cleared under 510(k) K141058.
- The intended use / patient population of both devices is the same – for use with an endoscope
- Device consists principally of an actuation handle and a flexible shaft body terminating in a pair of cutting Scissors
- Scissors function just like standard scissors for mechanical cutting. By operating the handle, the Scissors open and close.
- The main difference between the Ensizor™ Endoscopic Scissor and the predicate Ensizor™ Endoscopic Scissor is the addition to the indication for use of cutting sutures.

Comparison to K133736 - US Endoscopy Suture Cutter Device

- The intended use / patient population of both devices is the same – for use with an endoscope.
- Both devices consists principally of an actuation handle and a flexible shaft body terminating in a pair of cutting Scissors or jaws.
- The Suture Cutter device has jaws that can grasp and cut while the Ensizor™ Endoscopic scissor blades can only cut.

The intended use of cutting sutures is the same. Safety and effectiveness are not affected.

(7) **Performance Data:**

Ensizor™ Endoscopic Scissor – K141069

The following nonclinical testing was performed as part of the original Ensizor™ Endoscopic Scissor 510(k) submission.

- Operation in Tortuosity – each device shall open and close with the distal shaft of the device is formed into approximately a 20 cm or 8 in diameter circle.

This test simulated operation of the device in a flexible endoscope. The results of the tests shows that the Ensizor™ Endoscopic Scissor is substantially equivalent to the predicate devices tested as they actuated as good as or better than the predicate devices in a tortuous path.

- Sample Cutting – Each device shall cut at least 10 times each of the following sample materials:
 - o LDPE Polyethylene Sheet
 - o Polypropylene Suture
 - o Vicryl Suture
 - o Polydioxanone Suture
 - o Silk Sutures

All units met the requirement of cutting each material at least 10 times.

Comparative Testing – US Endoscopy Suture Cutter (Ref K133736 test results)

- Functional Testing – the ability of the jaws to the US Endoscopy Endoscopic Suture Cutter Device to open and close repetitively. After operation in a straight configuration the endoscope was reconfigured into a tortuous pathway and functional testing repeated.

All units met the acceptance criteria of being able to open and close in straight and tortuous conditions to perform the simulation of cutting and removing sutures from the human body.

- Simulation testing – the ability of the US Endoscopy Endoscopic Suture Cutter Device to function under simulated real use conditions to grasp and cut.
 - o 0, 3-0 Vicryl
 - o 0, 3-0 Prolene
 - o 0, 3-0 Silk

All units met the acceptance criteria of being able to effectively cut, grasp and remove suture.

510(k) Summary - Testing Summary

Criteria	Ensizor™ Endoscopic Scissors	US Endoscopy Endoscopic Suture Cutter Device
Operation in Tortuosity	Pass	Pass
Suture Cutting	Pass	Pass

(8) Conclusions:

Based on the non-clinical performance data performed comparing Ensizor™ Endoscopic Scissors to the predicate device, it is concluded that the data supports the safety of the device and the hardware verification demonstrate that the Ensizor™ Endoscopic Scissors should perform as intended in the specified use conditions. The data demonstrates that the Ensizor™ Endoscopic Scissors device performs substantially equivalent to the predicate device that is currently marketed for the same intended use.