



June 29, 2018

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

Re: K180134  
Trade/Device Name: Ensizor Monopolar Endoscopic Scissors  
Regulation Number: 21 CFR 876.4300  
Regulation Name: Endoscopic electrosurgical unit and accessories  
Regulatory Class: Class II  
Product Code: KGE, OCZ  
Dated: May 30, 2018  
Received: May 30, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for  
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)

K180134

Device Name

Ensizor® Monopolar Endoscopic Scissors

Indications for Use (Describe)

Ensizor® Monopolar Endoscopic Scissors are designed to cut and dissect tissue, cauterize tissue, cut sutures and cut non-metallic materials 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 Court  
Miami Lakes, FL 33014  
Telephone: (305) 889-3350  
Contact: John Starkey, COO / VP Quality Assurance  
Jan 10, 2018

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

|                                |                                                    |
|--------------------------------|----------------------------------------------------|
| <u>Proprietary/Trade Name:</u> | Ensizor <sup>®</sup> Monopolar Endoscopic Scissors |
| <u>Common Name:</u>            | Forceps, Biopsy, Electric                          |
| <u>Regulation Number</u>       | 876.4300                                           |
| <u>Regulation Name:</u>        | Endoscopic electrosurgical unit and accessories.   |
| <u>Classification Panel</u>    | Gastroenterology/Urology                           |
| <u>Product Code:</u>           | KGE, OCZ                                           |
| <u>Regulatory Class:</u>       | II                                                 |

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

The Ensizor<sup>®</sup> Monopolar Endoscopic Scissors is substantially equivalent to the Ensizor<sup>®</sup> Endoscopic Scissors (K150939) and the Apollo Endosurgery Endoscopic Scissors (K090583).

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

Ensizor<sup>®</sup> Monopolar Endoscopic Scissors

- Cat # MES-26165 2.6 mm Monopolar Endoscopic Scissors x 165cm insertion length
- Cat # MES-26235 2.6 mm Monopolar Endoscopic Scissors x 235cm insertion length

The Ensizor<sup>®</sup> Monopolar Endoscopic Scissors is a single-use ethylene oxide sterile electrosurgical scissors. This device is designed to be used with an electrosurgical monopolar HF generator to cut and dissect tissue, cauterize tissue, cut sutures and cut non-metallic materials during all flexible endoscopic procedures.

The device is compatible with flexible endoscopes with a minimum channel diameter of 2.8 mm. The maximum insertion portion diameter is 2.6 mm, and insertion lengths are 165 cm and 235 cm. The patented Edge Flex™ technology used for the Scissor Blades ("Blades") enhances the cutting performance of this flexible endoscopic

scissors. The Ensizor's rotation feature enables accurate-radial positioning, and the nitinol actuator wire allows for tortuous endoscopic paths while minimizing loss of distal control. The Blades are designed with blunt tips to enable the atraumatic dissection of tissue planes and when closed, make a non-sharp rounded cauterizing surface.

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

Ensizor<sup>®</sup> Monopolar Endoscopic Scissors are designed to cut and dissect tissue, cauterize tissue, cut sutures and cut non-metallic materials during all flexible endoscopic procedures.

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

The Ensizor<sup>®</sup> Monopolar Endoscopic Scissors have the same technological characteristics as the predicate devices as described below:

- Devices are designed to dissect, cut and cauterize tissue during endoscopic procedures.
- Devices consist 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.

**(7) Performance Data:**

The following nonclinical testing was performed in order to evaluate the substantial equivalence of the Ensizor<sup>®</sup> Monopolar Endoscopic Scissors to the predicate devices.

**Table 2**  
**510(k) Summary - Testing Summary**

| Test                                       | Ensizor<br>Monopolar<br>Endoscopic<br>Scissors | Apollo<br>Endosurgery<br>Endoscopic<br>Monopolar<br>Scissors |
|--------------------------------------------|------------------------------------------------|--------------------------------------------------------------|
| Product Attribute Testing                  | All units passed                               | All units passed                                             |
| Product Performance Testing                | All units passed                               | All units passed                                             |
| Sample Cutting                             |                                                |                                                              |
| .008 In. thickness rubber (Dental Dam)     | All units passed                               | All units passed                                             |
| .002 In. thickness LDPE Polyethylene Sheet | All units passed                               | All units passed                                             |
| 2-0 Polydioxanone Suture                   | All units passed                               | All units passed                                             |
| 3-0 Polydioxanone Suture                   | All units passed                               | All units passed                                             |
| 2-0 Polypropylene Suture                   | All units passed                               | All units passed                                             |

| Test                                                                                                                                           | Ensizor<br>Monopolar<br>Endoscopic<br>Scissors | Apollo<br>Endosurgery<br>Endoscopic<br>Monopolar<br>Scissors |
|------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------|
| 3-0 Polypropylene Suture                                                                                                                       | All units passed                               | All units passed                                             |
| 2-0 Silk Sutures                                                                                                                               | All units passed                               | All units passed                                             |
| 3-0 Silk Sutures                                                                                                                               | All units passed                               | All units passed                                             |
| 2-0 Vicryl Sutures                                                                                                                             | All units passed                               | All units passed                                             |
| 3-0 Vicryl Sutures                                                                                                                             | All units passed                               | All units passed                                             |
| Raw chicken for the electrocautery<br>functionality test (cut at least 10 times each<br>sample material and 10 tissue cauterization<br>tests). | All units passed                               | All units passed                                             |
| Insulation Test                                                                                                                                | All units passed                               | All units passed                                             |

**(8) Conclusions:**

Based on the non-clinical performance data performed comparing the Ensizor<sup>®</sup> Monopolar Endoscopic Scissors to the predicate devices, it is concluded that the device is as safe, as effective, and performs as well as or better than the predicate devices.