1. Company Identification
   EndoChoice, Inc.
   11800 Wills Road
   Alpharetta, GA 30009
   Telephone (678) 708 4743
   FAX (678) 567 8218
   Establishment Registration: 300759133

2. Contact Person
   Daniel Hoefer
   Regulatory Affairs Manager

3. Device Name
   Commercial name: AutoBand Multiple Band Ligator
   Classification name: Hemorrhoidal Ligator

4. Device Classification
   Product Code: MND
   Regulation Number: 876.4400
   Class: II

5. Intended Use
   The AutoBand Multiple Band Ligator is used to band esophageal varices or hemorrhoids in the colon. The device is intended for single use only.

6. Device Description
   The AutoBand Multiple Band Ligator device consists of the applicator unit (including the band barrel, handle, activation wheel, wheel grip, beaded string, interior stainless steel trigger wire, and fixation arm), a fixation strap, and the ligation bands that are mounted on the barrel.

   The device is intended for single use and is supplied non-sterile. The ligation bands are intended for endoscopic placement in the esophagus or colon, with the trigger wire introduced through the biopsy port of the endoscope. Each AutoBand barrel is pre-loaded with seven bands. Models are manufactured for compatibility with either gastroscopes or colonoscopes. AutoBand model designations also are differentiated based on compatibility with different endoscope manufacturers.

7. Substantial Equivalence
   The device submitted for review is a modification of the Auto-Band Ligator (K083556, Scandimed International).
Changes to the device include a modification in materials specification of the ligation bands. The unmodified bands are composed of natural latex rubber, while in the modified device they are synthetic Polyisoprene. In addition, the modified device includes minor design changes to the beaded deployment strand and the wire locking assembly arm; each of these mechanical changes is intended to improve ligation band deployment performance.

As a result of the modification to the band material, the labeling of the device no longer includes a caution statement that the device may cause allergic reactions due to the presence of natural latex rubber. The labeling now includes the statement “Not made with natural latex rubber.”

The modified device is identical in terms of intended use, operating principle, performance, technology, energy used, and packaging.

See Table 1 below.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Auto-Band Ligator (Latex)</th>
<th>AutoBand Ligator (Non-latex)</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) number</td>
<td>K083556</td>
<td>Pending</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The Auto-Band Ligator is used to band esophageal varices or hemorrhoids in the colon.</td>
<td>The AutoBand Ligator is used to band esophageal varices or hemorrhoids in the colon.</td>
</tr>
<tr>
<td>Operation</td>
<td>Varices are aspirated into the band barrel. Once in the correct position, the band is then deployed over the varix (the elastic band will assure that blood flow into the varix is stopped).</td>
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</tr>
<tr>
<td>Ligator Wheel design</td>
<td>• Automatic Reverse</td>
<td>• Automatic Reverse</td>
</tr>
<tr>
<td></td>
<td>• The Ligator wheel is designed with start and stop positions to ensure that no more than one band is deployed at a time. When the band is deployed, the wheel head will go automatically to the start position.</td>
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</tr>
<tr>
<td></td>
<td>• The Ligator wheel has a locking arm so that the trigger cord is held in the correct position to facilitate fully controlled deployment of the band.</td>
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</tr>
<tr>
<td>Band Barrel design</td>
<td>• The transparent band barrel is loaded with the bands next to each other. Only one cord in the band barrel is used to deploy the bands. The band deployment cord is supplied with small glass pearl to ensure.</td>
<td>• The transparent band barrel is loaded with the bands next to each other. Only one cord in the band barrel is used to deploy the bands. The band deployment cord is supplied with small glass beads to ensure.</td>
</tr>
</tbody>
</table>
correct and effective deployment of the bands.

Ligator Body design

- Mounting of the wheel is on a flexible arm, which allows the device to be firmly fixed on the scope; this ensures a high level of stability and precision during the procedure

Number of bands

5, 6, 7, 8, or 10

Same

Materials

Band Barrel: Acrylic
Cord: Nylon
Band: Natural Latex Rubber
Pearl: Glass
Ligator Body: Polycarbonate
Loading wire: Stainless Steel

Band Barrel: Acrylic
Cord: Nylon
Band: Synthetic Polyisoprene
Pearl: Glass
Ligator Body: Polycarbonate
Loading wire: Stainless Steel

Patient Contact

Ligation Bands are surface devices contacting mucosal membranes for prolonged duration.

Ligation Bands are surface devices contacting mucosal membranes for prolonged duration.

Packaging

PET (Polyethylene Terephthalate) Blister Pack

PETG (Polyethylene Terephthalate Glycol) Blister Pack

Biocompatibility of Band

Ligation Bands material is cytotoxic when tested in accordance with ISO 10993-5:1999

Tested for sensitization, irritation, and cytotoxicity. Ligation Band material is cytotoxic when tested in accordance with ISO 10993-5:1999

Sterilization

Single Use
Non-Sterile

Single Use
Non-Sterile

TABLE 1

8. Non-clinical testing
The modified device has undergone both bench testing of performance and laboratory biocompatibility testing for Irritation, Sensitization, Cytotoxicity, and System toxicity, in accordance with ISO 10993-1. In addition, the materials in the synthetic Polyisoprene bands were tested in accordance with the ELISA inhibition assay (ASTM D6499-07) and the Allergen ELISA (ASTM D74727-08), with result showing that allergens clinically relevant to latex allergy are not present to within detection limits.

Other design changes resulted in completion of non-clinical functional verification testing.

9. Conclusion
The modified AutoBand Ligator is substantially equivalent to the unmodified predicate device listed above.
August 23, 2013

EndoChoice, Inc.
% Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K132535
	Trade/Device Name: AutoBand Ligator
	Regulation Number: 21 CFR § 876.4400
	Regulation Name: Hemorrhoidal ligator
	Regulatory Class: II
	Product Code: MND
	Dated: August 9, 2013
	Received: August 13, 2013

Dear Daniel Hoefer,

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” (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 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 -S

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): K132535

Device Name: AutoBand Ligator

Indications for Use:

The AutoBand Ligator is used to band esophageal varices or hemorrhoids in the colon.

Prescription Use _X_ AND/OR Over-The-Counter Use _______

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Herbert P. Lerner - S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K132535