DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 3, 2015

Endochoice, Inc.
Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Rd.
Alpharetta, GA 30009

Re: K152580
Trade/Device Name: Rescuenet™
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic and electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI, GCJ
Dated: September 9, 2015
Received: September 10, 2015

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K152580

Device Name
EndoChoice Retrieval Net

Indications for Use *(Describe)*
The retrieval net is intended for use in endoscopic retrieval of foreign objects, food bolus, tissue fragments and excised tissue such as polyps.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Traditional 510(k) Summary

## 1. Company Identification

EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Telephone (678) 708 4743
FAX (678) 878 3373
Establishment Registration: 3007591333

## 2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager

## 3. Device Name

| | |
|---|---|
| Trade name: | rescuenet™ |
| Common/Usual Name: | Retrieval Net |

## 4. Device Classification

| | |
|---|---|
| Common Name: | Retrieval Net |
| Classification: | Endoscopic electrosurgical unit and accessories, 21CFR § 876.4300 |
| Product Code: | FDI, GCJ |
| Committee: | Gastroenterology/Urology |

## 5. Intended Use

The Retrieval Net is intended for use in endoscopic retrieval of foreign objects, food bolus, tissue fragments and excised tissue such as polyps.

## 6. Device Description

The EndoChoice Retrieval Net is a disposable, single-use sterile device comprised of a flexible wire cable and snare loop with net which can be extended and retracted form the flexible outer sheath using a three ring handle. Objects are retrieved by advancing the finger rings of the handle to open the retracted net. The net is then endoscopically manipulated over the foreign object, food bolus, tissue fragment or excised tissue, in which the finger rings of the handle are retracted to close the net once the article has been retrieved.

# 7. Substantial Equivalence

## 7.1 Predicate devices

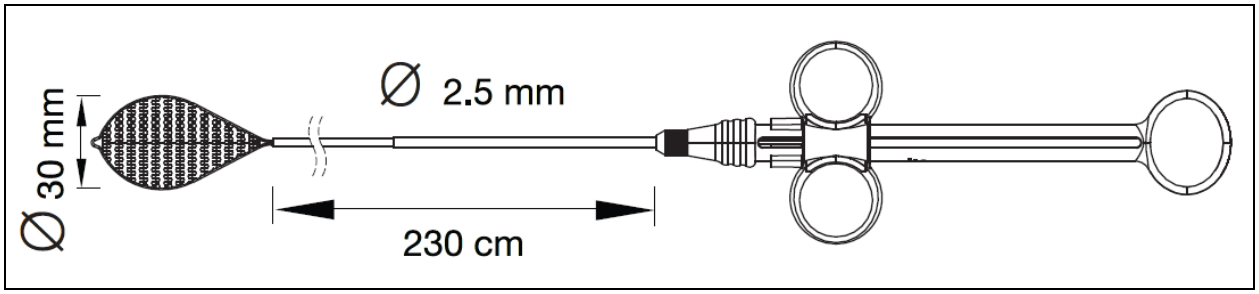
The EndoChoice retrieval net is substantially equivalent to the predicate device, the Roth Net® retriever product line by United States Endoscopy Group, Inc. The intended use, design and materials and labeling are all substantially equivalent.

## 7.2 Intended Use

The indications for use of the EndoChoice retrieval net is substantially equivalent to the predicate device, the Roth Net® retrieval product line (K122462) manufactured United States Endoscopy Group, Inc. In each case, the nets are intended for use in endoscopic retrieval of objects.

## 7.3 Technical Characteristics

The device length is 230cm and the device catheter diameter is 2.5mm.




## 7.4 Performance Characteristics

The steps for operator use of each of the devices are equivalent. The instructions for use describe how to use the device with a standard endoscope, in which the stepwise instructions are similar to that of the predicate device.

### 7.5 Substantial Equivalence Table

| Substantial Equivalence Comparison | | | |
|---|---|---|---|
| | **EndoChoice Retrieval Net** | **Roth Net® retriever product line (K122462)** | **Substantial Equivalence** |
| **Product Code** | *FDI, GCJ* | *FDI, GCJ* | *Identical* |
| **Regulation No.** | *21CFR § 876.4300* | *21CFR § 876.4300* | *Identical* |
| **Classification** | *Endoscopic electrosurgical unit and accessories* | *Endoscopic electrosurgical unit and accessories* | *Identical* |
| **Manufacturer** | *EndoChoice Inc.* | *United States Endoscopy Group, Inc.* | *N/A* |
| **Supplied Sterile** | *Yes* | *Yes* | *Identical* |
| **Sheath length** | *230cm* | *160cm, 230cm* | *Identical* |
| **Single use** | *Yes* | *Yes* | *Identical* |
| **Sheath diameter** | *2.5mm* | *2.5mm, 3.0mm* | *Identical* |
| **Compatibility** | *2.8mm endoscope channel* | *2.8mm, 3.2mm endoscope channel* | *Equivalent* |
| **Net Size** | *3 x 6 cm* | *3 x 6 cm*<br>*2 x 4.5 cm*<br>*4 x 5.5 cm*<br>*4 x 8 cm* | *Identical* |
| **Configuration** | *Oval* | *Oval, Octagonal, Hexagonal* | *Identical* |
| **Indications for use** | *This device is intended for use in endoscopic retrieval of foreign objects, food boluses, tissue fragments and excised tissue such as polyps.* | *The Roth Net® retriever product line is intended to be used to retrieve excised polyps, tissue samples, foreign bodies and calculi during flexible and rigid endoscopy procedures.* | *Equivalent* |
| **Packaging** | *Single-use pouch* | *Single-use pouch* | *Identical* |

## 8. Non-Clinical testing

### 8.1 Sterilization and Shelf-Life

The EndoChoice Retrieval Net is sterilized by Ethylene Oxide.
Validation has been completed in accordance with the following standards:

- ISO 11135: 2014 Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- AAMI ANSI ISO 11737-2: 2009 Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
- AAMI ANSI ISO 11138-1: 2006 Sterilization of Health Care Products - Biological Indicators - Part 1: General Requirements

The shelf life of the EndoChoice Retrieval Net is 1 year from date of manufacturing.

## 8.2 Biocompatibility

Results of Biocompatibility testing in accordance with AAMI ANSI ISO 10993-1: 2009 Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a Risk Management Process demonstrates that the device meets the requirements.

## 8.3 Performance Testing

Results from various performance testing indicates that the EndoChoice Retrieval Net functions as intended.

## 9. Conclusion

Retrieval nets have been in use for over 20 years. A variety of retrieval net devices are available on the market from different manufacturers with various diameters and lengths. Based on the above information, the EndoChoice Retrieval Net is substantially equivalent to the predicate device listed. The information contained in this submission supports the fact that the EndoChoice Retrieval Net is as safe and effective as its predicate device.