K122462

SEP 11 2012

Special 510(k) Information

Device Name

The device trade name and common/classification name is:

Device Trade Name: Roth Net® retriever product line
Common/Classification Name: Endoscope and accessories
Classification Panel: Gastroenterology/Urology

Address and Registration #

Manufacturer: United States Endoscopy Group, Inc.
5976 Heisley Road
Mentor, Ohio 44060
Registration #: 1528319

Device Class

Endoscope accessories are classified with Endoscopes as Class II devices under 21 CFR § 876.1500 (product code GCJ). No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for endoscope accessories.

Predicate Device Information

The predicate device is the US Endoscopy Polyp Snare Net (AKA, the Roth Net® retriever), cleared under 510(k) K926104 on April 5, 1993.

Labeling and Intended Use

Since introduction of the Polyp Snare Net in 1993, the device Instructions for Use (which now carries the Roth Net® brand name) have been revised and Warning and Precaution statements were added for clarity to ensure safe and effective use. Instructions for Use can be found beginning on page 29.

Intended Use

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. This is the same intended use as specified in the device labeling and the cleared 510(k) under K926104, April 5, 1993. This intended use has not changed, or in any way been affected, as a result of the warning and precaution modifications. None of the modifications affected the device's indications.

The Indications for Use Statement can be found on page 16.

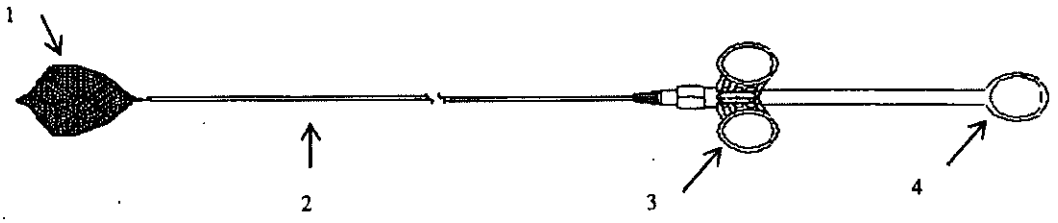
Device Description and Comparison of Legally Marketed Devices

General Description

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. The device is marketed in both sterile and non-sterile versions.

The fundamental design and technology of the Roth Net® retriever are the same as the predicate Polyp Snare Net originally submitted under K926104 with the exception of the changes listed below. The device consists of a proximal handle with a finger ring that controls the deployment of the fabric mesh basket (a wire snare with a fabric net attached). The snare/net is connected to a drive wire, which is then connected to the handle. The drive wire is encompassed within a sheath that makes up the catheter.

Below is a representative drawing of the Roth Net® retriever.



1. Snare/Net (deployed)
2. Catheter
3. Finger ring
4. Handle

Description of Modified Device

Subsequent to FDA's determination that the Polyp Snare Net was substantially equivalent to legally marketed predicate devices under 510(k) K926104 on April 5, 1993, US Endoscopy implemented modifications to the device that are summarized below in Table 1. Each modification was reviewed and documented by US Endoscopy in accordance with Company procedures and processes regarding post-market product modifications and the guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device" (K97-1).

The modified Roth Net® retriever has the same intended use and same fundamental technological characteristics as the predicate Polyp Snare Net device. Each

modification was determined not to have a significant effect on the safety or effectiveness of the device, either individually and cumulatively. Determination that the modifications do not affect the performance characteristics of the device was accomplished through verification and validation testing, incorporating all device modifications made to date. This testing demonstrated that the modified device performs the same as the device cleared under K926104.

Summary of Design Control Activities

The risk management activities used to assess the impact of the modifications were performed in accordance with US Endoscopy standard operating procedures and ISO 14971:2009. The test methods used are the same as those used to test the predicate device reviewed under K926104. A declaration of conformity to design controls is included on page 26. The design verification tests that were performed as a result of this risk analysis are listed in Table 1 below.

TABLE 1 – Design Control Activities Summary

Device Modification	Reason for Modification	Risk/ Hazard	Mitigation	Verification Activity	Acceptance Criteria	Verification Results
Changes for Clinical Ease of Use						
Change in snare shape from round to octagonal and change in snare loop wire shape (braided cable to flat wire)	To better allow the loop to maintain its shape; and allow for greater capacity.	Inability to grasp objects; net will not open fully	Verification testing of the deployment and retraction forces; test device's ability to grasp objects	Deployment and retraction workability testing Simulated use testing for grasping ability	Force required to deploy and retract shall be ≤ 3.25 lbs. Net can be fully retracted without any parts left outside of the sheath. Net can be fully deployed without exposing the proximal end of the connector. Must maintain ability to grasp and retrieve simulated polyps and foreign bodies	**PASS**
Change in the mesh size of the net	To improve the visibility when capturing multiple polyp fragments.	Inability to grasp objects; inability to visualize net once objects grasped.	Verification of device's ability to grasp objects and maintain visibility.	Grasp testing using simulated polyps and foreign bodies Simulated use testing to verify that there is no obstruction of endoscopic visibility	Net is capable of securing material that measures 2cm x 1.5cm x 2.5cm. Visualization of pouch and its contents are not obstructed	**PASS**
Dimensional Changes						
Increased length and diameter of device sheath/catheter	Allow use of subject device with various endoscopes[1]	Inadequate fit to the enteroscope (length); catheter collapse (columnar strength); non-deployment of the device. Inability to push device through accessory channel of the endoscope; kinking of the catheter	Dimensional and functional testing; kink resistance testing. Testing of insertion and retraction forces; resistance to kinking	Dimensional Verification Testing Kink testing. Simulate use testing by inserting the devices through an enteroscope and grasping a variety of items. Insertion and extraction force testing	Length shall be 138.00 ± 2.5 inches (350.5 ± 6.35 cm) Visible plastic deformation due to compression must not occur in an insertion column length of 1.5 in (3.8 cm) through the accessory channel of the endoscope. Device shall capture simulated food bolus, foreign bodies or polyps while maintaining structural integrity. Insertion force of less than or equal to 2.5 lbs. Extraction force of less than or equal to 2.5 lbs.	**PASS**

[1] Since introduction of the Polyp Snare Net in 1993, the variety of endoscopes for GI use has expanded considerably. Additional catheter lengths and diameters were added to accommodate new endoscopes using the same basic design and technology of the original Polyp Snare Net.

Device Modification	Reason for Modification	Risk/ Hazard	Mitigation	Verification Activity	Acceptance Criteria	Verification Results
Dimensional Changes						
Net size change to largest size: 8 cm (l) x 4 cm (w)	To allow device to be used with endoscopes with larger channels	Net fails to deploy completely	Verification testing of the ability of net to deploy	Simulated use testing to verify net deployment and retraction force Verification of deployed net length and width	Max deployment/retraction force shall be ≤ 3.25lbs The length of the fully deployed net shall be 2.59 – 3.29 inches (6.6 – 8.4 cm.) The width of the fully deployed net shall be 1.41 – 2.10 inches (3.6 – 5.3 cm.)	**PASS**
Changes for Increased Manufacturing Efficiency						
A chamfer melt was added on the inside of the catheter	To maintain the smooth transition of the snare/net into the catheter when the snare/net is retracted	Difficulty in deployment and/or retraction	Verification testing of the force required to deploy and retract the net	Deployment and retraction force testing	Max deployment force shall be ≤ 3.25lbs Max retraction force shall be ≤ 3.25lbs	**PASS**
Change in the mesh configuration to add bidirectional mesh	Increased manufacturability	Inability to grasp objects.	Verification testing of the device's ability to continue to grasp simulated polyps	Functional testing the net	Grasp the objects and held securely in the net. Beads are captured and controlled.	**PASS**
Change in the length of the wire loop ends of the snare loop assembly and a change in the flat wire bond to the drive-wire form	To facilitate the change from a crimp to a resistance welding connection	Weld breaks	Tensile strength testing	Test connection between drive cable to wire form of the snare loop (30 devices)	Tensile pull must be ≥ 12 lbs	**PASS**

Device Modification	Reason for Modification	Risk/ Hazard	Mitigation	Verification Activity	Acceptance Criteria	Verification Results
Changes for Increased Manufacturing Efficiency						
Addition of a mesh net tail on the distal and proximal sides of the net	Eliminate the need for thread as an anchor to prevent net cinching	Net cinches up.	Verification testing	Simulated use testing to verify cinching does not occur	Nets shall not cinch. Proximal and distal anchors shall remain intact.	**PASS**
Material Change						
The catheter material was modified from tetrafluoro-ethylene (TFE) to polyethylene (PE) to reduce cost without reducing performance	Cost Reduction	Loss of biocompatibility	Verification testing for acute systemic toxicity, cytotoxicity and irritation and delayed hypersensi-tivity	Test in accordance with ISO 10993-5, 10 and -11	Material shall show no reactivity in test subjects	**PASS**
Appearance Change						
Change handle color from white to silver	Add new color to distinguish between standard and platinum models	No risks were identified in relation to this modification. No performance data were required because a change in color of the handle does not affect performance of the subject device.				

Substantial Equivalence Discussion

All currently marketed Roth Net® retriever devices share the same intended use and same fundamental technological characteristics as the US Endoscopy predicate Polyp Snare Net device cleared by the Agency under K926104. Verification and validation testing performed for each modification to the Roth Net® device demonstrates that these changes, both individually and cumulatively, do not have a significant effect on the safety or effectiveness of the device, do not raise different questions of safety and effectiveness than the predicate device and verify the Roth Net® device performs the same as the predicate device. Therefore, we conclude that the Roth Net® device is substantially equivalent to the predicate Polyp Snare Net device.

510(k) Summary /Statement — A 510(k) statement is included on page 17.

Truthful and Accurate Statement — A certification of the truthfulness and accuracy of this submission is provided on page 18.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Craig Moore
General Counsel
United States Endoscopy Group, Inc.
5976 Heisley Road
MENTOR OH 44060

SEP 11 2012

Re: K122462
Trade/Device Name: Roth Net® retriever product line
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI, GCJ
Dated: August 10, 2012
Received: August 13, 2012

Dear Mr. Moore:

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" (21CFR 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,

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): K122462

Device Name: Roth Net® retriever product line

Indications for Use:

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122462