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

June 27, 2016

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

Re: K161482
Trade/Device Name: EndoChoice Water Bottle Cap Irrigation System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FEQ
Dated: May 26, 2016
Received: May 31, 2016

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,

Joyce M. Whang -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)*
K161482

Device Name
EndoChoice Water Bottle Cap Irrigation System

Indications for Use *(Describe)*
The water bottle cap irrigation system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

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.

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510(k) Summary
EndoChoice Water Bottle Cap Irrigation System

1. Company Identification

Applicant:
EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Establishment Registration: 3007591333

2. Contact Person

Daniel Hoefer
Sr. Regulatory Affairs Manager
EndoChoice, Inc.

3. Device Name

Trade name:	EndoChoice Water Bottle Cap Irrigation System
Common/Usual Name:	Water Bottle Cap Irrigation System
Classification name:	FEQ; Endoscope and Accessories

4. Device Classification

Classification	Endoscope and accessories, 21CFR 876.1500
Product Code:	FEQ
Committee:	Gastroenterology/Urology

5. Intended Use

The water bottle cap irrigation system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

6. Device Description

The EndoChoice Water Bottle Cap Irrigation System is a sterile, consumable, 24-hour multi-patient use device designed to fit commercially available sterile water bottles and irrigation pumps for providing sterile water during endoscopic procedures.

The EndoChoice water bottle cap system is comprised of a polycarbonate standard water bottle cap, medical grade PVC tubing that extends from the endoscope connector into the water bottle, and a medical grade stainless steel cylinder that serves

as both the water intake portion of the disposable water bottle cap and a weight to hold the tubing down while in the water bottle.

The bottle tubing is added into the sterile water bottle and the irrigation system is fastened via the tubing system cap.

Flexible pump tubing connected to the top of the water bottle cap runs to the tubing connector reducer. This flexible tubing is the part of the device that is placed into the irrigation pump. A tubing connector reducer joins the flexible tubing and rigid tubing. The rigid tubing runs to the tubing Luer connector. The tubing Luer connector has the first one-way check valve which prevents potential backflow of fluid from the endoscope into the tubing set. The separately packaged, single-use endoscope connectors (used to connect the tubing set to the auxiliary water channel) also contain one-way valves used to prevent potential backflow.

As with the predicate, the separately packaged, single-use connectors are used to connect to different endoscope models, and all include the second one-way valve to prevent contamination due to potential backflow.

Between patients, the endoscope connectors must be changed to ensure that there is no risk of cross contamination. EndoChoice water bottle irrigation tubing fits standard threaded lid disposable sterile water bottles of approximately 33 mm diameter.

The water bottle cap system is supplied sterile and can be used up to 24 hours.

7. Substantial Equivalence

The modified EndoChoice Water Bottle Cap Irrigation System is equivalent to the legally marketed unmodified EndoChoice Water Bottle Cap Irrigation System (K133747). A feature comparison of the two devices is shown below.

Based on the intended use, technological characteristics and overall performance of the devices, EndoChoice, Inc. believes that the modifications to the EndoChoice Water Bottle Cap Irrigation System leave the device equivalent to the unmodified predicate and that the differences between the devices do not raise new issues of safety or effectiveness.

Comparison Table		
	EndoChoice Water Bottle Cap Irrigation System (Unmodified)	**EndoChoice Water Bottle Cap Irrigation System (Modified)**
510(k) number	K133747	Pending
Compatibility with currently available endoscopes	Olympus 140, 160, 180, Endoscopes	Olympus 140, 160, 180, And Fuse Endoscopes
Sterilization Method	Ethylene Oxide	Unchanged
Compatibility with commercially available sterile water bottles	Compatible with Standard 33 mm water bottle caps	Unchanged
Compatibility with Olympus OFP-2 irrigation pumps	N/A	Compatible
Indications for use statement	The water bottle cap irrigation system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	Unchanged
Contraindications	Those specific to any endoscopic procedure	Unchanged
Materials (patient contacting)		
Flexible Pump Tubing	PVC - Flexchem	PVC – APEX, change in PVC formulation, equivalent to previous formulation
Flexible Pump Tubing dimensions	Outer diameter 6.4 mm, inner diameter 3.2mm	Outer diameter 9.7 mm, inner diameter 6.5 mm
Compression Luer Connector / Reducer	Polycarbonate, Makrolon 2558	Polycarbonate, PC 110, equivalent to previous formulation
Rigid Tubing	PVC, MD80-GS-PVC	Unchanged
Tubing Connector Reducer	Polycarbonate, Makrolon 2558	Polycarbonate, Makrolon 2458, change in formulation, equivalent to previous formulation
Bottle Tubing	PVC 5420	PVC 3304A, change in PVC formulation, equivalent to previous formulation
Bottle Tubing Weight	Stainless Steel Grade 303	Stainless Steel Grade 304, change in stainless steel formulation, equivalent to previous formulation
Male Luer Base	PC110	Polycarbonate Makrolon 2458, change in formulation, equivalent to previous formulation
Female Luer Connector	PC110	Unchanged

Comparison Table		
	EndoChoice Water Bottle Cap Irrigation System (Unmodified)	**EndoChoice Water Bottle Cap Irrigation System (Modified)**
Materials (no patient contact) / Use		
Packaging	Individually packaged in Tyvek Peel Pouch	Unchanged
Tyvek package	Dimension: 320 mm x 150 mm, part# 1059B	Dimension: 340 mm x 240 mm, part# 1073B, dimensional change and Tyvek type change are equivalent to previous package
Use	Disposable, 24-hour multi-patient use	Unchanged

8. Non-clinical testing

Non-clinical testing has been performed on the device. Specifically, the following has been completed on the accessory water bottle, cap, and tubing:

- Benchtop functional performance testing, post-aging
- Biocompatibility testing in conformance with ISO 10993-1

All test results passed, demonstrating that the device is safe and effective in comparison with the predicate device.

9. Conclusion

The modified EndoChoice Water Bottle Cap Irrigation System is equivalent to the legally marketed predicate device. It is the same or equivalent in terms of design, intended use, materials, and labeling.