

Special 510(k) Summary

1. Company Identification

EndoChoice, Inc.
11800 Wills Road
Alpharetta, GA 30009
Telephone (678) 708 4743
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Establishment Registration: 300759133

2. Contact Person

Daniel Hoefler
Regulatory Affairs Manager

3. Device Name

Trade name: EndoChoice Water Bottle Cap Irrigation System
Common/Usual Name: Water bottle cap irrigation system
Classification name: Endoscopic irrigation/suction system

4. Device Classification

Common Name: Colonoscope and accessories, flexible / rigid
Classification: Endoscope 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 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 in the water bottle.

Flexible pump tubing of larger diameter is connected to the top of the water bottle cap and runs to the tubing compression ring. This flexible tubing is the part of the device that is placed into the irrigation pump. From the tubing compression ring, more rigid tubing

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runs to the rigid tubing luer connector and the one way check valve which prevents reverse direction fluid from the endoscope into the tubing set. Once connected, the device provides flow of sterile irrigation water during endoscopy procedures.

Connectors / accessories are used to connect to the different endoscopes. Between patients, the endoscope connectors must be changed to ensure that there is no risk of cross contamination.

A female luer connector is used to connect the device to the series 160 / 180 Olympus endoscopes. Customers may use a luered blunt needle to connect to series 140 endoscopes. The cap of the system and associated tubing is connected to standard bottles, providing sterile water to rinse tissue for improved viewing and access. The water bottle cap system is supplied sterile and can be used up to 24 hours.

EndoChoice water bottle irrigation tubing fits standard threaded lid disposable sterile water bottles. The device can be used with any peristaltic irrigation pump that accepts industry standard irrigation tubing.

7. Substantial Equivalence

7.1. Predicate devices

The modified EndoChoice Water Bottle Cap Irrigation System is substantially equivalent to the unmodified EndoChoice Water bottle (K120862) manufactured by EndoChoice, Inc. The intended use, design, materials and labeling are all substantially equivalent.

This submission has been prepared to address changes in the materials to the tubing, which have been made to improve manufacturing yield of the device and to limit the amount of irrigation water that is emitted after the pump's foot pedal control has been deactivated.

7.2. Intended Use

The indications for use the device under review is the same as the predicate unmodified EndoChoice Water bottle (K120862) manufactured by EndoChoice. In each case, 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.

7.3. Technical Characteristics

Like the predicate device, the modified 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 in the water bottle.

Flexible pump tubing of larger diameter is connected to the top of the water bottle cap and runs to the tubing compression ring. This flexible tubing is the part of the device that is placed into the irrigation pump. From the tubing compression ring, more rigid tubing runs to the rigid tubing luer connector and the one way check valve which prevents reverse direction fluid from the endoscope into the tubing set. Once connected, the device provides flow of sterile irrigation water during endoscopy procedures.

Connectors / accessories are used to connect to different endoscope models, including Olympus series 160, 180, and 190, and Fusc endoscopes. Between patients, the endoscope connectors must be changed to ensure that there is no risk of cross contamination.

The cap of the system and associated tubing is connected to standard bottles, providing sterile water to rinse tissue for improved viewing and access. The water bottle cap system is supplied sterile and can be used up to 24 hours.

EndoChoice water bottle irrigation tubing fits standard threaded lid disposable sterile water bottles. The device can be used with any peristaltic irrigation pump that that accepts tubing of approximately 5/16 inch diameter (8mm).

Changes to the device include the material formulation and supplier of the tubing each type of tubing that comprises the device (see below), and inner diameter and outer diameter changes to the flexible tubing.

7.4. Performance Characteristics

The steps for operator use of each of the devices are equivalent. The instructions for use describe how to connect the device to standard endoscopes using connector assemblies, which are unchanged from the predicate. The device is also connected via the threaded water bottle cap to standard sterile water bottles, with the water intake tubing inserted into the bottle. The user then can use a footswitch-controlled irrigation pump to provide irrigation during endoscopy procedures.

7.5. Substantial Equivalence Table

Comparison with Predicate Device			
	EndoChoice Water Bottle Cap Irrigation System (Predicate)	Modification to EndoChoice Water Bottle Cap Irrigation System	Substantial equivalence
Manufacturer	EndoChoice, Inc.	EndoChoice, Inc.	identical
510k number	K120862	Pending	
Compatibility with	Olympus series 160,	Olympus 160, 180,	Equivalent

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currently available endoscopes	180, 190	190	
Supplied Sterile	Yes	Yes	identical
Intended use	Single-use up to 24 hours (connectors single patient use)	Single-use up to 24 hours (connectors single patient use)	identical
Operating principle	Peristaltic irrigation pump attached to flexible tubing draws sterile irrigation water through tubing inserted into bottle and connected to irrigation port of endoscope	Peristaltic irrigation pump attached to flexible tubing draws sterile irrigation water through tubing inserted into bottle and connected to irrigation port of endoscope	identical
Patient Contacting Materials:			
- Flexible Pump Tubing	PVC ME62	PVC Flexchem 5051-02	Similar: Change in formulation of PVC
- Joint Connector	PC1100	Polycarbonate - Makrolon 2558	Similar: Change in formulation of polycarbonate
- Rigid Tubing	PVC 5420	PVC MD80-GS-PVC	Similar: Change in formulation of PVC
- Rigid Tubing Luer Connector	PVC 5420	Polycarbonate - Makrolon 2558	Similar: Change from PVC to polycarbonate
- Bottle Tubing	PVC 5420	Same	identical
- Bottle Tubing Weight	Stainless Steel	Same	identical
- Male Luer Base	PC1100	Same	identical
- Female luer connector	PC1100	Same	identical
Compatibility with commercially available sterile water bottles	Yes	Yes	Identical
Indications for use statement	The EndoChoice water bottle cap system	The EndoChoice water bottle cap system	identical

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	(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.	(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.	
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8. Non-clinical testing

The following non-clinical testing has been performed on the modified EndoChoice Water Bottle Cap Irrigation System:

- Benchtop functional performance testing
- Biocompatibility testing in conformance with ISO 10993-1.

All test results passed, demonstrating that the safety and efficacy is equivalent to the predicate device.

9. Conclusion

The EndoChoice Water Bottle Cap Irrigation System is substantially equivalent to the predicate devices listed above. It is the same or equivalent in terms of design, intended use, materials, and labeling.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 8, 2014

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

Re: K133747
Trade/Device Name: EndoChoice Water Bottle Cap Irrigation System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: December 6, 2013
Received: December 9, 2013

Dear Daniel Hoefler,

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,

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): K133747

Device Name: EndoChoice Water Bottle Cap Irrigation System

Indications for 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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
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