



Food and Drug Administration  
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February 24, 2016

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

Re: K153588  
Trade/Device Name: EndoChoice Water Bottle Cap System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: FEQ  
Dated: January 22, 2016  
Received: January 27, 2016

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 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

## Indications for Use

510(k) Number (if known)

K153588

Device Name

EndoChoice Water bottle cap system

Indications for Use (Describe)

The EndoChoice water bottle cap system is intended to be used with an air source or carbon dioxide (CO<sub>2</sub>) with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with commercially available sterile water bottles.

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.

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## **510(k) Summary**

### **EndoChoice Water Bottle Cap System**

#### **1. Company Identification**

**Applicant:**

EndoChoice, Inc.  
11810 Wills Road  
Alpharetta, GA 30009

**Establishment Registration:** 3007591333

#### **2. Contact Person**

Daniel Hoefler  
Regulatory Affairs Manager  
EndoChoice, Inc.

#### **3. Device Name**

Trade name:	EndoChoice Water Bottle Cap System
Common/Usual Name:	Water bottle cap 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 EndoChoice water bottle cap system is intended to be used with an air source or carbon dioxide (CO<sub>2</sub>) with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with commercially available sterile water bottles.

#### **6. Device Description**

The EndoChoice water bottle cap system is a sterile disposable device designed to fit commercially available sterile water bottles for providing sterile water during endoscopic procedures. The water bottle cap system is designed with a clip that is placed on the tubing to stop water flow from the water bottle when the endoscope is not in use.

The device attaches via a connector to the air/water port of an endoscope. The water bottle cap itself is attached to a standard sterile water bottle. Air supplied from the processor unit then pressurizes the water bottle, providing water flow when the air/water valve of the endoscope is depressed. Some models provide a feature that provides an option to use a CO<sub>2</sub> air source. Instructions state that the device is to be used by trained endoscopy professionals.

## 7. Substantial Equivalence

The modified EndoChoice Water Bottle Cap System is substantially equivalent to the legally marketed unmodified EndoChoice Water Bottle Cap System (K142155). 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 system* leave the device substantially equivalent to the unmodified predicate and that the differences between the devices do not raise new issues of safety or effectiveness.

<b>Comparison Table</b>		
	<b>EndoChoice Water Bottle Cap System (Unmodified)</b>	<b>EndoChoice Water Bottle Cap System (Modified)</b>
510(k) number	K142155	K153588
Compatibility with currently available endoscopes	Olympus 140, 160, 180, and Fuse Endoscopes	Olympus 140, 160, 180, and Fuse Endoscopes
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Compatibility with commercially available sterile water bottles	Compatible with Standard 33 mm water bottle caps	Unchanged
Indications for use statement	The EndoChoice water bottle cap system is intended to be used with an air source from an endoscope with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with commercially available sterile water bottles.	Unchanged
Contraindications	Those specific to any endoscopic procedure	Unchanged
Materials (patient contacting)	PC-110, Stainless Steel, PVC, TPE	PC-110, Stainless Steel, PVC (not manufactured with materials that contain DEHP), TPE
Materials (no patient contact)	TPE 2109-35, Polypropylene, HDPE, LDPE, , adhesive paper, NBR	Unchanged
Packaging	Individually packaged in Tyvek Peel Pouch	Unchanged
Use	Disposable, maximum use 24 hours	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 System is equivalent to the legally marketed predicate device. It is the same or equivalent in terms of design, intended use, materials, and labeling.