NOV 27 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	EndoChoice, Inc. 11810 Wills Rd, Suite 100 Alpharetta, GA 30009
Contact Person:	Theron Gober Quality and Regulatory Manager
Phone Number:	678-534-6021
Fax Number:	770-962-6981
Establishment Registration Number:	300759133
Date Prepared:	March 12, 2012
Device Trade Name(s):	EndoChoice Water bottle cap irrigation system:
Device Common Name:	Water bottle cap irrigation system
Classification Name:	FEQ; Endoscope and accessories
Predicate Device(s):	*Byrne Medical, Inc. EndoGator System (K092429)*
General Device Description:	The EndoChoice water bottle cap irrigation system is designed to supply sterile water when used in conjunction with an irrigation pump.
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.
Technological Characteristics:	From a clinical perspective and comparing design specifications, the EndoChoice water bottle cap irrigation system and the predicate device are substantially equivalent. Based on the technological characteristics and overall performance of the device, EndoChoice, Inc. believes that no significant differences exist between the proposed water bottle cap irrigation system and the predicate device. EndoChoice, Inc. believes the minor differences of the water

bottle cap system *and* its predicate device should not raise any concerns regarding the overall safety or effectiveness.

Performance Data: The device and the predicate device performance were tested using a simulated setup for water flow rate and device leakage. The proposed device demonstrated equivalent performance when compared to the predicate device. The device also was subjected to testing that simulated device wear to ensure the device would function effectively for up to 24 hours use.

Conclusion: Based on the technological characteristics and overall performance of the devices, EndoChoice, Inc. believes that the *water bottle cap irrigation system* and the predicate device selected are substantially equivalent and that the differences between the devices are minor which do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 27, 2012

EndoChoice, Inc.
% Mr. Theron Gober
Director, RA / QA
11810 Wills Road, Suite 100
ALPHARETTA GA 30009

Re: K120862
Trade/Device Name: Water Bottle cap irrigation system
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: October 12, 2012
Received: October 17, 2012

Dear Mr. Gober:

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 -S

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): K120862

Device Name: 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120862