K112576

JAN 25 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:	December 8, 2010
Device Trade Name(s):	EndoChoice Water bottle cap system:
Device Common Name:	Water bottle cap system
Classification Name:	FEQ; Endoscope and accessories
Predicate Device(s):	*United States Endoscopy Water bottle cap system (K101146)*
General Device Description:	The EndoChoice water bottle cap system is designed to supply sterile water and air to the endoscope during endoscopic procedures.
Intended Use:	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.
Technological Characteristics:	From a clinical perspective and comparing design specifications, the EndoChoice water bottle cap system and the predicate device are substantially equivalent. Based on the technological characteristics and overall performance of the devices, EndoChoice, Inc. believes that no significant differences exist between the proposed water bottle cap 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:	We tested our EndoChoice Water Bottle Cap System to ensure that our system performs as well as the predicate device. The testing included sufficient water flow through the system over multiple uses without leaking.
Biocompatibility Data:	The EndoChoice Water Bottle Cap System was tested for biocompatibility in accordance with ISO 10993.
Conclusion:	Based on the technological characteristics and overall performance of the devices, EndoChoice, Inc. believes that the *water bottle cap 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Theron Gober
RA / QA Manager
EndoChoice, Inc.
11810 Wills Rd, Suite 100
ALPHARETTA GA 30009

JAN 25 2012

Re: K112576
Trade/Device Name: Water Bottle cap system
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: December 27, 2011
Received: December 29, 2011

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, 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): K112576

Device Name: Water Bottle cap system

Indications for Use

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.

(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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112576