MEDIVATORS
A Cantel Medical Company

JUL 15 2014

Endo Smart Bottle

Section 05. 510(k) Summary

Manufacturer:	Medivators, A Cantel Medical Company
Address:	3150 Pollok Dr, Conroe, TX – 77303
	(963) 539-0391
Official Contact:	Kinnari Shah, MS
	Regulatory Affairs Specialist
Trade Name:	Endo Smart Bottle, Rinse and Insufflation System
Common Name:	Endoscopic Irrigation/Suction System
Classification Name:	Endoscope and accessories
Product Code:	OCX
Device Class:	II
Classification Regulation:	876.1500

Medivators Inc. has supplied the following information to the US Food and Drug Administration to support substantial equivalence of Endo Smart Bottle, Rinse and Insufflation System to its predicate - Endoscope accessories – Endo Smart Cap.

1. **Device Description**

Endo Smart Bottle is designed to be attached to an endoscope, to help supply water, air/CO_2. The device consists of a connector cap, a water bottle, a threaded cap, a small tube, and a male luer. The main function of the subject device is –

- To provide water for rinsing the lens.
- To provide air or CO_2 to insufflate the anatomical lumen, to help the end user to see the inner wall more clearly.

Similar to its predicate device, the subject device is provided sterile to the end user, fabricated from plastics, and elastomers, intended for daily (24 hour) multi-patient use and must be discarded daily. Both the subject device and its predicate device do not come in direct contact with patients.

MEDIVATORS
A Cantel Medical Company

5. Conclusion

Medivators has provided appropriate premarket notification information in the form of a 510(k) to support the substantial equivalence of Endo Smart Bottle to legally marketed predicate device. The information and performance data provided indicates that the Endo Smart Bottle is safe and effective for its intended use when used in accordance with the device labeling.

2. Intended Use

The EndoSmart Bottle is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.

3. Comparison to Other Devices in Commercial Distribution Within the United States

Endo SmartBottle is equivalent in function, intended use and technology to Medivators Endo SmartCap cleared under 510k – K093665. Endo SmartBottle is closely related to its predicate device - Endo SmartCap.

Both the predicate device and the subject device have the same intended use, principle of operation and scientific technology. Only difference between the 2 devices is – Endo Smart Bottle has concise tubing and an integrated water bottle unlike its predicate. Endo SmartCap and Endo Smart Bottle are daily (24 hour) disposable version of reusable analogues predicate of Endo SmartCap, this eliminating the risk of disinfection. A predicate device comparison table which supports substantial equivalence of Endo SmartBottle to its predicate is contained in the Substantial Equivalence section of this submission.

4. Summary of Non-Clinical Performance Data

Medivators has conducted the following conformance testing to demonstrate that Endo Smart Bottle has performance characteristics equivalent to its predicate Endo Smart Cap –

- Design Verification including functional testing –
  - Lens Rinsing Function
  - Insufflation Function
  - Safety
- Biocompatibility
  - Cytotoxicity Evaluation
  - Intracutaneous Irritation Test
  - Sensitization
- Shelf-life validation
  - Functional Testing
  - Dye Penetration Testing
  - Peel Strength Testing
  - Visual Seal Inspection
- Sterilization validation

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

July 15, 2014

Medivators, Inc.
Kinnari Shah
Regulatory Affairs Specialist
14605 28th Ave N
Minneapolis, MN 55447

Re: K140753
Trade/Device Name: Endo Smart Bottle System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCX
Dated: March 25, 2014
Received: March 26, 2014

Dear Kinnari Shah,

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

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 on last page.

510(k) Number *(if known)*
K140753

Device Name
Endo Smart Bottle

Indications for Use *(Describe)*

The EndoSmart Bottle is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Benjamin R. Fisher -S
2014.07.15 11:11:52 -04'00'

PSC Publishing Services (301) 443-6740 EF

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."