ERBE USA Incorporated
Traditional 510(k): ERBEFLO CleverCap™ Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes

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510(k) SUMMARY

MAR 2 2 2011

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal QA/RA Manager
Date Prepared:	December 16, 2010
Common Name:	Endoscopic Irrigation Tubing Set and Water Bottle Adaptor
Trade/Proprietary Name:	ERBEFLO CleverCap™ Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes
Classification Name:	Endoscopes And/or Accessories (21 CFR Part 876.1500)
Product Code:	KOG
Legally Marketed Predicate Device:	EndoGator® System, 510(k) Number K092429 and Endo SmartCap®, K093665

EndoGator and Endo SmartCap are registered trademarks of Byrne Medical, Inc.

Device Description:
The ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes consist of two (2) tubing segments and a cap. The cap of a Set attaches with an air-tight seal to a water source (i.e., a sterile water bottle). Then from the water bottle, irrigation tubing of a Set interfaces with a designated pump and via ERBEFLO 2 connector accessories to a specified Olympus® Scope for endoscopic lavage. The other segment, the air/water tubing, also coming from the same water bottle; connects to an air/water port of a specified Olympus® Scope for air intubation as well as lens cleaning (Note: The air/water tubing is a tube within a tube in which the endoscope's air/water processor pressures the bottle for water flow.). Both the irrigation as well as the air/water tubing segments have a backflow valve and a clamp to pinch off the tubing while not in use. Each Set is designed for use with designated irrigation pumps and have a air/water connector for specified Olympus® Scopes. The Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes are provided sterile and are disposable.

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Olympus is a registered trademark of the Olympus Corporation

Intended Use:
The ERBEFLO CleverCap Hybrid Tubing/Cap Sets provide sterile water and air from a single source to an endoscope for endoscopic procedures.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):
Similarities
The ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes have the same basic intended use of both of the predicates combined. The proposed Sets have the same thread connections, cap, tubing segments, and back flow valve placement. The tubing of the Hybrid Sets also has comparable Durometer, Inner Diameters (I.D.s), and Outer Diameters (O.D.s) as the predicate devices. The proposed and predicate devices also both have the same locking clamp and tubing weight insert. The length of the air/water segment is the same with the Hybrid Sets as compared to the Endo SmartCap. The Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes have the same duration of use as the EndoGator System as well as Endo SmartCap (24 hour use). The proposed Sets and predicate devices use the same types of water bottles, pumps, endoscope connection accessories, and endoscope. Finally, the proposed and predicate devices are sterilized via Ethylene Oxide and disposable.
Differences
The predicate devices (i.e., the EndoGator System and Endo SmartCap) can also be used with additional pumps and endoscopes as well as have capability of using CO_2 instead of air for intubation. To address these differences, the ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes Notes On Use specifies designated pumps and Olympus® Scopes for use as well as only has instructions for use with the air/water processor of the Scopes. The types of materials used for the ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes are similar to the predicates (EndoGator System and Endo SmartCap) but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes was evaluated. See Section III, Product Data - Biocompatibility Study. The predicates are two separate products used to do the same function of the proposed device. The Hybrid Sets also use only one water source as compared to the predicates each having a respective water source. Additionally, the irrigation tubing of the ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes is a longer single PVC piece as compared to EndoGator Tubing being a shorter 3-segment piece with a silicone portion interfacing with a pump head (Note: The segment of the proposed device also has a clamp and the predicate Tubing does not.). Also, the air/water tubing of the ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes has a back flow valve as compared

to the predicate Endo SmartCap that does not have a valve. Nonetheless with the differences in the physical and dimensional aspects of the proposed Sets as compared to the combined predicate devices; performance testing demonstrated improved flow rates as well as equivalent back flow pressure, internal pressure, and durability. See Section III, Product Data - Performance Testing.

Conclusion:
The ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes intended use is a part of both of the predicate's indications in the previously cleared 510(k)s. The proposed Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes have the same principles of operation and technological characteristics as the predicate devices combined. The duration of use for the proposed and predicates is the same. As compared to the predicates, the proposed Sets are constructed with the same type of materials as well as have enhanced flow rates as well as comparable back flow pressure, internal pressure, and durability characteristics. In conclusion, all the differences were verified or validated. As a result, the ERBEFLO CleverCap Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes did not adversely affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. John Tartal
QA/RA Manager
ERBE USA, Inc.
2225 Northwest Parkway
MARIETTA GA 30067

MAR 22 2011

Re: K103696
Trade/Device Name: ERBEFLOW CleverCap™ Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: March 3, 2011
Received: March 4, 2011

Dear Mr. Tartal:

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.

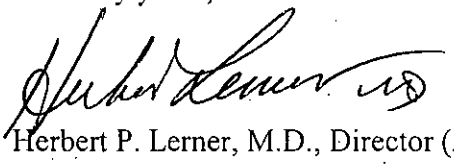
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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, M.D., Director (Acting)
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): K103696

Device Name: ERBE USA, Inc.'s ERBEFLO CleverCap™ 2 Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes

Indications For Use:

The ERBEFLO CleverCap™ Hybrid Tubing/Cap Sets provide sterile water and air from a single source to an endoscope for endoscopic procedures.

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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103696