K103235
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ERBE USA Incorporated
Traditional 510(k): ERBEFLO™ 2 Disposable Tubing System

DEC 2 3 2010

510(k) SUMMARY

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:	October 29, 2010
Common Name:	Endoscopic Irrigation Tubing System
Trade/Proprietary Name:	ERBEFLO™ 2 Disposable Tubing System
Classification Name:	Endoscopes And/or Accessories (21 CFR Part 876.1500)
Product Code:	KOG
Legally Marketed Predicate Device:	EndoGator® System, 510(k) Number K924102

EndoGator is a registered trademark of Byrne Medical, Inc.

Device Description:

The ERBEFLO™ 2 Disposable Tubing System consists of tubing sets, port connectors, channel adapter, and backflow valve to deliver sterile water from a water source through designated pumps and to/or through a scope channel of various endoscopes. Clinicians connect the associated Product(s)/Component(s) to a water source (i.e., a sterile water bottle) and then to a designated pump and endoscope. The ERBEFLO™ 2 Disposable Tubing System is provided sterile and is disposable.

Intended Use:

The ERBEFLO™ 2 Disposable Tubing System is intended to provide sterile water from a water source through an irrigation pump and an endoscope (or to an endoscope) for endoscopic procedures.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities
The ERBEFLO™ 2 Disposable Tubing System has the same basic intended use as the predicate. The Systems have the same thread connections, vented cap, tubing segments, and back flow valve placements. The tubing of each System also has the same Inner Diameter (ID), Outer Diameter (OD), and Durometer. They also both have the same locking collars, pump head tubing segment length, and tubing weight insert. Also, the accessories are the same. Products/Components of each System have the same durations of use. Both Systems use the same types of water bottles, pumps, and endoscopes. Both of the components/products of each System are sterilized via Ethylene Oxide and are disposable.

Difference
The predicate device (i.e., the EndoGator® System) can also be used with pumps having a cartridge as well as pumps with a pump head. To address this issue, the ERBEFLO™ 2 Disposable Tubing System Notes On Use specifies designated pumps. The types of materials used for the ERBEFLO™ 2 Disposable Tubing System are similar to the predicate (EndoGator® System) but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Products/Components of the ERBEFLO™ 2 Disposable Tubing System was evaluated. See Section III, Product Data - Biocompatibility Study. The physical aspects and overall length of the proposed System were comparable to the predicate System but not identical. Therefore performance testing involving flow rates, back flow pressure, internal pressure, and durability testing was performed on the ERBEFLO™ 2 Disposable Tubing System. See Section III, Product Data - Performance Testing.

Conclusion:

The ERBEFLO™ 2 Disposable Tubing System's intended use is a part of the predicate's indications in the previously cleared 510(k). The ERBEFLO™ 2 Disposable Tubing System has the same principles of operation and technological characteristics as the predicate device. The duration of use for both Systems is the same. As compared to the predicate, the proposed System is constructed with the same type of materials as well as comparable dimensional, flow, back flow pressure, internal pressure, and durability characteristics. In conclusion, all the changes were verified or validated. As a result, the ERBEFLO™ 2 Disposable Tubing System 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
Quality Assurance/Regulatory Affairs Manager
ERBE USA, Inc.
Surgical Systems
2225 Northwest Parkway
MARIETTA GA 30067

DEC 2 3 2010

Re: K103235
Trade/Device Name: ERBEFLO™ 2 Disposable Tubing System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: October 29, 2010
Received: November 2, 2010

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

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Indications for Use

510(k) Number (if known): K103235

Device Name: ERBE USA, Inc.'s ERBEFLO™ 2 Disposable Tubing System

Indications For Use:

The ERBEFLO™ 2 Disposable Tubing System is intended to provide sterile water from a water source through an irrigation pump and an endoscope (or 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 K103235