ERBE USA, Inc.
Traditional 510(k)/Third Party Review:
ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube

DEC 17 2013

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 Director
Date Prepared:	May 22, 2013
Common Name:	Endoscopic Irrigation and CO_2 or Air Tubing/Cap Sets and CO_2 Connector Tube
Trade/Proprietary Name:	ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube
Classification Name:	Endoscopes and Accessories (21 CFR Part 876.1500)
Product Code:	FEQ
Legally Marketed Predicate Device:	Universal Irrigation Solution Hybrid™, 510(k) Number K102855 and ERBEFLO CleverCap® Hybrid Tubing/Cap Sets, 510(k) Number K103696

Device Description:
In general; the Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tubes will be manufactured with medical grade materials or agents used in the medical device industry such as plastics, nickel plated brass, nitrile rubber, acrylic, nylon, ink, solvent, adhesive, etc. The devices provide as a conduit for water for endoscopic irrigation and lens cleaning as well as air or CO_2 for insufflation.
There are three (3) types of ERBEFLO CleverCap Hybrid CO_2Tubing/Cap Sets for which each respectively interfaces with a specified brand of scope (i.e., Pentax, Olympus, and Fujinon) along with one (1) CO_2 Connector Tube to attach to a CO_2 source. The Sets consist of multiple 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 cap, irrigation tubing of a Set interfaces with a designated pump and via ERBEFLO 2 connector accessories to the specified endoscope for endoscopic lavage. The next segment, the air/water tubing (also coming from the same water bottle cap), connects to an air/water port of a specified scope for air insufflation as well as lens cleaning [Note: The air/water tubing is a tube within a

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tube in which the endoscope's processor or CO_2 Source (if used) is used to pressurize the bottle for functionality (air and water to the endoscope). Also, for the Pentax Set there is an additional air inlet tube that directs air for endoscope functional use. Or if CO_2 is used, pressurization (air and water function) occurs via a CO_2 Source through a CO_2 Connector Tube and a Pentax CO_2 Adaptor (Pentax part #OF-G11).]. The third and final segment for both the Olympus and Fujinon Sets is for connecting to the CO_2 Connector Tube for CO_2 insufflation. For each Set, both the irrigation as well as the air/water tubing segments have a backflow valve and a clamp to close the tubing while not in use. Additionally, each Set is designed for use with designated irrigation pumps and has an air/water connector(s) for its specified endoscope. The Hybrid CO_2Tubing/Cap Sets are provided sterile and are disposable.
The CO_2 Connector Tube has a standard female luer connector for accessing a CO_2 Source. The other end of the Tube has a hydrophobic air/gas filter which filters particulates from the CO_2 Source and keeps fluid from flowing into the CO_2 Source. The filtered end of the CO_2 Connector Tube attaches to the CO_2 segments of the Sets or in the case of the Pentax Set, the Pentax CO_2 Adaptor that adjoins the Set to the Endoscope. The CO_2 Connector Tube is provided non-sterile and is disposable.

Intended Use:
The ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube provide sterile water and CO_2 or air (if CO_2 is not used) to an endoscope for endoscopic procedures.

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

Similarities

The ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Sets have the same intended use as the Universal Irrigation Solution Hybrid™ Sets and a similar intended use to the ERBEFLO CleverCap Hybrid Tubing/Cap Sets. The proposed Sets have the same thread connections, cap, tubing segments, and valve placements in comparison to one or both of the predicates. The tubing of the Hybrid CO_2 Sets has the same or comparable durometer, Inner Diameters (I.D.s), Outer Diameters (O.D.s), and lengths as the predicate devices. The proposed and predicate devices both have the same locking clamp. Also, the Hybrid Tubing/Cap Sets have the same duration of use as the predicate devices (24 hour use). The proposed Sets and predicate devices use the same types of water bottles, pumps, endoscope connection accessories, endoscopes, and CO_2 sources. Finally, the proposed and predicate devices are sterilized via Ethylene Oxide and disposable.

The ERBEFLO CleverCap CO_2 Connector Tube compared to Universal Irrigation Solution Hybrid™ CO_2 Source Tubing in that both are manufactured with similar materials, are provided non sterile, have the same luer fittings and a hydrophobic

air/gas filter, and are used in the same manner for the same duration.

Differences

For the Sets, there is one difference not covered by either predicate. The ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Set will have a luer actuated valve on the CO_2 access tube as compared to the predicate device which has a backflow valve. Evaluations and testing as described below demonstrated the safety and efficacy of this Set.

The ERBEFLO CleverCap CO_2 Connector Tube is different than the Universal Irrigation Solution Hybrid™ CO_2 Source Tubing in that it is one piece (i.e., it is not in segments), it is shorter in length, and its filter is not as prominent (i.e., a smaller footprint). None of these differences impacted the safety or efficacy of the ERBEFLO CleverCap CO_2 Connector Tube.

Evaluations and Testing:

The following evaluations and tests were performed on the ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube to demonstrate the safety and efficacy.

Biological Evaluation

The evaluation was performed per the current recognized standard and demonstrated that there were no biocompatibility issues with the materials used for the proposed products.

Performance Feasibility Testing

The feasibility testing showed that the flow performance of the proposed products was as good or better than the predicate devices.

Flow Rate Testing

Flow rates for irrigation and lens cleaning were found to be comparable to or better than the predicate devices and/or commercially available products.

Pressure Testing

The pressure testing demonstrated that the proposed devices would withstand maximum internal pressures that could be encountered during normal use.

Durability Testing

The products were tested and proved durable for 24 hour use.

2X Sterilization Functional Testing

The testing demonstrated that the proposed products upon 2X sterilization met established performance specifications.

Packaging Evaluation

The evaluation demonstrated the adequacy and integrity of the packaging for the proposed products.

Sterilization Evaluation

The evaluation was performed using current recognized standards to demonstrate product sterility.

Conclusion:

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The ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube's intended use is the same, although written differently, as the Universal Irrigation Solution Hybrid™ predicate. Also, the proposed device's intended use is similar to the ERBEFLO CleverCap Hybrid Tubing/Cap Sets with exception of the CO_2 access/use addition. The proposed Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube have the same principles of operation and technological characteristics as the predicate devices. 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 comparable performance characteristics. In conclusion, the ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube did not adversely affect 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 20993-0002

December 17, 2013

ERBE USA, Inc.
% Mark Job
Responsible Third Party
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K132340
Trade/Device Name: ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and Accessories
Regulatory Class: Class II
Product Code: FEQ
Dated: November 27, 2013
Received: December 2, 2013

Dear Mark Job:

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 contact 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. 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 -S

for
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): K132340

Device Name: ERBE USA, Inc.'s ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube

Indications For Use:

The ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube provide sterile water and CO_2 or air (if CO_2 is not used) 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)

Herbert P. Lerner -S
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