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

August 31, 2016

Erbe USA, Inc.
John Tartal
Director of Quality
and Regulatory Affairs
2225 Northwest Parkway
Marietta, GA 30067

Re: K162152
Trade/Device Name: Erbe's CO_2 Tubing/Cap Sets
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEQ
Dated: July 29, 2016
Received: August 2, 2016

Dear John 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 contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

For Division

Douglas Silverstein -S
2016.08.31 12:09:18 -04'00'

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 below.

510(k) Number *(if known)*
K162152

Device Name
Erbe's CO2 Tubing/Cap Sets

Indications for Use *(Describe)*
Erbe's CO2 Tubing/Cap Sets provide sterile water and CO2 or air (if CO2 is not used) to an endoscope for 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

Submitted By: Erbe USA, Inc.
2225 Northwest Parkway
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Tel: 770-955-4400
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Contact Person: John Tartal
Director of Quality and Regulatory Affairs

Date Prepared: July 29, 2016

Common Name: Endoscopic CO_2 Tubing/Cap Sets

Trade/Proprietary Names: Erbe's CO_2 Tubing/Cap Sets (i.e., ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and ERBEFLO AeroRinse® CO_2 and Water Tubing/Cap Sets)

Classification Name: Endoscopes and Accessories (21 CFR Part 876.1500)

Product Code: FEQ

Legally Marketed Predicate Device: ERBEFLO CleverCap® Hybrid CO_2 Tubing/Cap Sets and Connector Tube, 510(k) Number K132340

Device Description:
In general; Erbe's CO_2 Tubing/Cap Sets will be manufactured with medical grade materials or agents used in the medical device industry such as plastics, silicone, nickel plated brass, nitrile rubber, acrylic, nylon, ink, solvent, adhesive, etc. The ERBEFLO CleverCap® CO_2 devices provide a conduit for water for endoscopic irrigation and lens cleaning as well as air or CO_2 for insufflation; whereas, the ERBEFLO AeroRinse® CO_2 devices provide a conduit for water for endoscopic lens cleaning as well as air or CO_2 for insufflation. There are three (3) types of Erbe's CO_2 Tubing/Cap Sets for each group (i.e., ERBEFLO CleverCap® CO_2 and ERBEFLO AeroRinse® CO_2) which each respectively interfaces with a specified brand of scope (i.e., Pentax, Olympus, and Fujinon Gastrointestinal video Endoscopes). There are two subsets of Sets for the Olympus scope in aech group; one that attaches to standard CO_2 sources and the other which specifically attaches to an Olympus CO_2 Unit Model UCR. 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 (as applicable- only for the ERBEFLO CleverCap® CO_2 Sets) interfaces with a designated pump and via ERBEFLO 2 single use 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 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 the Set's CO_2 segment.]. The third and final segment for both the Olympus and

Fujinon Sets is for connecting to a CO_2 Source for CO_2 insufflation. For each Set, both the irrigation (as applicable) as well as the air/water tubing segments has a backflow valve. The CO_2 segment of the Sets have a standard female luer connector for access a CO_2 Source or in the case of specified Olympus Sets there is a connector on the CO_2 segment designed to accessing the Olympus CO_2 Unit Model UCR. All of the CO_2 segments have a hydrophobic air/gas filter which filters particulates from the CO_2 Source and keeps fluid from flowing into the CO_2 Source. The irrigation (as applicable), air/water, and CO_2 segments of the Sets have a clamp to close off the tubing while not in use. Additionally, each Set has an air/water connector(s) for its specified endoscope. Erbe's CO_2 Tubing/Cap Sets are provided sterile and are disposable.

Intended Use:

Erbe's CO_2 Tubing/Cap Sets 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

Erbe's CO_2 Tubing/Cap Sets have the same intended use as the predicate device (i.e., the ERBEFLO CleverCap Hybrid CO_2 Tubing/Cap Sets and Connector Tube). The proposed Sets have the same materials and basic design as the predicate devices. The modified 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 (as applicable), endoscope connection accessories, endoscopes, and CO_2 sources. Finally, the proposed and predicate devices are sterilized via Ethylene Oxide and disposable.

Differences

Modified Sets (i.e., the ERBEFLO AeroRinse® CO_2) were created to eliminate the irrigation line/segment. Also, the CO_2 segment on the Sets was modified to have the Sets directly connect to a CO_2 Source (i.e., "A CO_2 Connector Tube" was included as part of the Sets). Included in the CO_2 segment modification was replacing the actuvator valve with a connector and clamp. Additionally, Olympus Sets were created to directly connect to the Olympus CO_2 Unit Model UCR. Finally, for standardization purposes the packaging configuration was changed to have 10 Sets per shelf box. Evaluations and testing as described below demonstrated the safety and efficacy of the Sets.

Evaluations and Testing:

The following evaluations and tests were performed to demonstrate 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.

2X Sterilization Package Integrity and Functional Testing

Package integrity testing, visual inspection, flow testing, back flow pressure testing, pressure decay testing, tensile strength testing, durability testing (including ensuring no leaks and connectability upon stressing Sets), and clamp 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 as well as Sets meeting ethylene oxide residual requirements.
Applied Standards
AAMI / ANSI / ISO 10993-1, ISO 594-1, ISO 594-2, AAMI / ANSI / ISO 15223-1, AAMI / ANSI / ISO 11607-1, AAMI / ANSI / ISO 11607-2, AAMI / ANSI / ISO 11135(-1), AAMI / ANSI / ISO 10993-7

Conclusion:
Erbe's CO_2 Tubing/Cap Sets intended use is the same as the Hybrid CO_2 Tubing/Cap Sets and CO_2 Connector Tube. The proposed Sets 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 predicate, the proposed Sets are constructed with the same type of materials and as applicable have the same performance characteristics. In conclusion, Erbe's CO_2 Tubing/Cap Sets did not adversely affect safety or effectiveness.