August 11, 2022

Erbe USA, Inc.
Jeff Dill
Senior Quality Engineer
2225 Northwest Parkway
Marietta, GA 30067

Re: K221177
Trade/Device Name: Erbe's Tubing/Cap Sets
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: July 8, 2022
Received: July 11, 2022

Dear Jeff Dill:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221177

Device Name
Erbe's Tubing/Cap Sets

Indications for Use *(Describe)*
The Erbe Tubing/Cap/Cap Sets provide sterile water and air from a single source 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: Jeff Dill
Senior Quality Engineer

Date Prepared: April 21, 2022

Common Name: Endoscopic Tubing/Cap Sets

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

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

Regulatory Class: II

Product Code: OCX

Legally Marketed Predicate Devices: ERBEFLO CleverCap™ Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes, 510(k) Number K103696 and Erbe's CO_2 Tubing/Cap Sets, 510(k) Number K162152

Device Description:
Erbe's Tubing/Cap Sets are manufactured with medical grade materials or agents used in the medical device industry such as plastics, brass, adhesive, etc. The ERBEFLO CleverCap® devices provide a conduit for water for endoscopic irrigation and lens cleaning as well as air for insufflation; whereas, the ERBEFLO AeroRinse® devices provide a conduit for water for endoscopic lens cleaning as well as air for insufflation. There are four (4) and three (3) variants of Erbe's Tubing/Cap Sets for each group respectively (i.e., ERBEFLO CleverCap® and ERBEFLO AeroRinse®). All of the Sets respectively interface with a specified brand of scope (i.e., Pentax®, Olympus®, Fujifilm®, and Fujinon® Gastrointestinal Video Endoscopes). The Sets consist of tubing segment(s) 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, an irrigation tubing line (segment) of a Set (as applicable- only for the ERBEFLO CleverCap® Sets) interfaces with a designated peristaltic pump and via an ERBEFLO connector accessory attaches 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 endoscope for air insufflation as well as lens cleaning [Note: The air/water tubing is a tube within a tube in which the endoscope is used to pressurize the water bottle for functionality (air and water to the endoscope)]. Also, for the Pentax Set there is an additional air inlet tube that directs air from the endoscope's processor. For each Set, the irrigation tubing segment (as applicable) as well as the air/water tubing segment has a back flow check valve. The irrigation (as applicable) and air/water 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 Tubing/Cap Sets are provided sterile and are disposable.

Intended Use:
The Erbe 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 Device (Predicate Comparison/Substantial Equivalence):

Similarities

Erbe's Tubing/Cap Sets in this 510(k) are essentially the same (i.e., materials, construction, dimensionally, etc.) as the Sets in the previously cleared 510(k)s. The intended use is the same as the primary predicate (ERBEFLO CleverCap™ Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes). The additional Sets in the submission are essentially the same as the second predicate (Erbe's CO_2 Tubing/Cap Sets) but without the CO_2 tubing line (segment)/feature. The Sets have the same intended use, sterilization, use conditions, disposability, etc.

Differences

There are primarily two (2) differences as follows:

1. The main difference involves the addition of a more automated packaging system for pouching and labeling the Sets (i.e., currently packaging Sets in a pouch and proposed packaging Sets in a soft pouch tray). Package integrity with the new system was verified as described below.
2. Minor change of creating a Hybrid Tubing/Cap Set for the new Fujifilm Scopes (700 Series Endoscope). The air/water scope connector is slightly different than the Set for the Fujinon Scope so that it fits (attaches/detaches) to the new Scope Series. Inspection/Testing demonstrated that the Set met specifications as described below.

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 Sets.

2X Sterilization Functional Testing

Visual inspection, flow testing, back flow pressure testing, pressure decay testing, tensile strength testing, connection testing, and durability testing (including ensuring no leaks and connectability upon stressing Sets) confirmed that the Devices upon 2X sterilization met established performance specifications.

Packaging Inspection/Testing

Current pouching of the products maintained their integrity [Note: Inspection/Testing of the pouch (sterile barrier) was included in many of the previous ERBEFLO cleared 510(k)s including the predicate submissions. Visual packaging inspection as well as dye penetration, burst, and seal strength testing were used to evaluate, qualify the various size pouches]. For the new automated packaging system; inspection (visual for package integrity and barcode readability), dye penetration, bubble leak testing, burst testing, seal strength tensile testing) were performed on soft pouch trays upon 2X sterilization (as well as after handling/transit simulation), and upon aging. Inspection/Testing demonstrated the suitability of the new pouch trays for the Sets.

Sterilization Evaluation
The evaluation was performed using the current recognized standard to demonstrate product sterility as well as that the products met ethylene oxide residual requirements.

Applied Standards
ISO 14971, 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 Tubing/Cap Sets intended use is the same as the ERBEFLO CleverCap™ Hybrid Tubing/Cap Sets for Olympus® Model 160 and 180 Series Scopes. The proposed Sets have the same principles of operation and technological characteristics as the predicate devices. The duration of use for the proposed and predicate Sets is the same. As compared to the predicates, the proposed Sets are constructed with the same type of materials and as applicable have the same performance characteristics. Additionally, the packaging (pouches or soft pouch trays) of the products have been found to maintain their sterile barrier. In conclusion, Erbe's Tubing/Cap Sets are safe and efficacious.