May 23, 2019

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

Re: K190469
Trade/Device Name: ERBEFLO® 2 Disposable Tubing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: February 23, 2019
Received: February 26, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Shani Haugen, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190469

Device Name
ERBEFLO® 2 Disposable Tubing System

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
Director of Quality and Regulatory Affairs

Date Prepared: February 23, 2019

Common Name: Endoscopic Irrigation Tubing System

Trade/Proprietary Names: ERBEFLO® 2 Disposable Tubing System

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

Regulatory Class: II

Product Code: OCX

Legally Marketed Predicate Device: ERBEFLO® 2 Disposable Tubing System, 510(k) Number K103235

Device Description:
The ERBEFLO® 2 Disposable Tubing System products are manufactured with medical grade materials or agents used in the medical device industry such as plastics, brass, adhesive, etc. The devices consist of tubing sets, port connectors, channel adapter, and back flow valve to deliver sterile water from a water source through designated pumps and to/or through a scope channel of various endoscopes for irrigation in endoscopy procedures. Clinicians connect the associated products to a water source (i.e., a sterile water bottle) and then to a designated pump and endoscope. The products in the ERBEFLO® 2 Disposable Tubing System are provided sterile and are 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 Device (Predicate Comparison/Substantial Equivalence):

Similarities

The ERBEFLO® 2 Disposable Tubing System products in this 510(k) are essentially the same (i.e., materials, construction, dimensionally, etc.) as the products in the previously cleared 510(k). The intended use, packaging, sterilization, use conditions, disposability, etc. are the same.

Differences

The ERBEFLO® 2 Disposable Tubing System Notes On Use's (i.e., the Labeling) Precautions and Warnings section is being updated to better inform users of potential hazards. Additionally, a back flow (check) valve is being added to the 24 hour use Endoscopy Port Connectors for Olympus® and Pentax® Scopes [Note: When Erbe scope accessories (i.e., connectors, channel adapter, and back flow valve) are used with Erbe tubing sets there will be two (2) back flow (check) valves. The redundant back flow protection features with Erbe products will provide an additional layer of protection to prevent back flow from occurring that could cause possible patient-to-patient cross contamination and infection.]. These measures are being taken to warn against the use of Erbe products with other manufacturer's tubing products that are not specified in Erbe's Notes On Use (NOU), provide more clarity involving the importance of priming the scope channel and maintaining the water barrier in the scope channel, as well as mitigate risk if Connectors are used "off label" (i.e., use of non-Erbe tubing products not specified in Erbe's NOU). Fundamentally from a product design prospective, the single use Endoscopy Port Connector w/Valve for Olympus® Scopes submitted/cleared in the original 510(k) is also being packaged and labeled as the 24 hour use Endoscopy Port Connector for Olympus® Scopes and the single use Endoscopy Port Connector w/Valve for Pentax® Scopes submitted/cleared in the original 510(k) is also being packaged and labeled as the 24 hour use Endoscopy Port Connector for Pentax® Scopes (i.e., there is no product design change that hasn't already been reviewed/cleared. The changes are a designation/labeling change for both Connectors.).

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 products in the ERBEFLO® 2 Disposable Tubing System.

2X Sterilization Functional Testing

Visual inspection, flow testing, back flow pressure testing, tensile strength testing, durability testing, and connections testing demonstrated that the devices upon 2X sterilization met established performance specifications.

ERBEFLO® 2 Endoscopy Port Connectors for Pentax® Scopes 2X Sterilization Functional Testing

Visual inspection and connections testing upon aging demonstrated that the devices upon 2X sterilization met established performance specifications.

Packaging Evaluation

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

Sterilization Evaluation

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

Barrier Integrity and Simulated Use Testing

The testing showed that Erbe port connectors when used with an Erbe tubing set provides sufficient back flow protection and verified 24 hour multi-patient use.

Human Factors Engineering/Usability Engineering Testing

The evaluation testing demonstrated that Erbe's port connectors can be used as intended by following ERBEFLO® 2 Disposable Tubing System's Notes On Use.

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:
The ERBEFLO® 2 Disposable Tubing System is safe and efficacious.