June 27, 2019

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

Re: K191438
Trade/Device Name: ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCX
Dated: May 29, 2019
Received: May 30, 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/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,

for
Shanil P. 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)*
K191438

Device Name
ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector

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.

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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:	May 29, 2019
Common Name:	Endoscopic Irrigation Tubing System Accessory/Scope Port Connector
Trade/Proprietary Name:	ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector
Classification Name:	Endoscopes and accessories (21 CFR Part 876.1500)
Regulatory Class:	II
Product Code:	OCX
Legally Marketed Predicate Device:	ERBEFLO® 2 Endo QuickConnect Scope Port Connectors, 510(k) Number K143186

Device Description:
In general; the ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector will be manufactured with materials or agents that can be used in the medical device industry such as plastics, silicone, solvent, etc. The device adjoins an irrigation line of an of an ERBEFLO Tubing/Cap Set designated for a Pentax Scope to a Pentax Gastrointestinal Video Endoscope with a forward water jet channel for irrigation in endoscopic procedures. The Port Connector has a standard female luer lock connection that attaches to a designated ERBEFLO Tubing/Cap Set for Pentax Scopes, back flow (check) valve, and housing (a scope specific connector for a Pentax Scope). The Port Connector is provided sterile, is single patient use, 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.

Note: The ERBEFLO 2 Endo Quick Connect Pentax Scope Port Connector is an accessory/single use connector for the ERBEFLO® 2 Disposable Tubing System.

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

Similarities

The proposed ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector is dimensionally the same from an exterior point of view as the current Connector with the same backflow valve, packaged the same, sterilized the same via Ethylene Oxide, single use (i.e., use for a patient), and is disposable like the predicate device.

Differences

The proposed ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector is different than the predicate in that its Port Connector housing is manufactured with a different plastic resin. Additionally since the last submission, there were some minor internal changes in which the core depth was increased along with a slight increase to the ring seal. Evaluations and testing as described below demonstrated the safety and efficacy of the Port Connector.

Evaluations and Testing:

The following evaluations and tests 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 Port Connector.

2X Sterilization Functional Testing

Visual inspection, connections testing, as well as leak and flow testing demonstrated that the proposed device upon 2X sterilization met established performance specifications.

Sterilization Evaluation

The evaluation was performed using current recognized standards and demonstrates product sterility as well as the Connector meets ethylene oxide residual requirements.

Applied Standards (or as applicable adoption of previous work regarding a standard)

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 proposed device has the same intended use (i.e., single patient use), principles of operation, and technological characteristics as the predicate device. As compared to the predicate, the proposed Connector is constructed with the same type of materials as well as has the same performance characteristics. In conclusion, the ERBEFLO® 2 Endo Quick Connect Pentax® Scope Port Connector is safe and efficacious.