



U.S. FOOD & DRUG
ADMINISTRATION

August 5, 2021

United States Endoscopy Group, Inc
Carroll Martin
Regulatory Affairs Director
5976 Heisley Road
Mentor, OH 44060

Re: K191559

Trade/Device Name: AquaShield System CO₂, AquaShield System PENTAX, AquaShield System
CO₂-PENTAX, AquaShield System CO₂-FUJIFILM

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and Accessories

Regulatory Class: Class II

Product Code: FEQ

Dear Carroll Martin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 1, 2019. Specifically, FDA is updating this SE Letter as an administrative correction to the trade names listed in the Indications for Use (IFU) form.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shanil Haugen, Ph.D., DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices, 301-796-0301, shanil.haugen@fda.hhs.gov.

Sincerely,

Shanil P. Haugen -S

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



August 1, 2019

United States Endoscopy Group, Inc
Carroll Martin
Director, Regulatory Affairs
5976 Heisley Road
Mentor, OH 44060

Re: K191559
Trade/Device Name: AquaShield System CO₂, AquaShield System CO₂-PENTAX,
AquaShield System CO₂-FUJIFILM
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FEQ
Dated: June 11, 2019
Received: June 13, 2019

Dear Carroll Martin:

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,

**Martha W.
Betz -S**

Digitally signed by Martha
W. Betz -S
Date: 2019.08.01 10:19:55
-04'00'

Martha Betz, Ph.D.
Acting Assistant Division 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

Indications for Use

510(k) Number (if known)

K191559

Device Name

AquaShield System CO2, AquaShield System PENTAX, AquaShield System CO2-PENTAX,, AquaShield System CO2-FUJIFILM

Indications for Use (Describe)

The AquaShield CO2 System is intended to be used with an air or carbon dioxide (CO2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with U.S. commercially available water bottles.

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.

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