June 11, 2026

FloShield, Inc.
% Trudie Seeger
CEO
Advance BioReg, Inc.
4170 Bowmansroot Court
Hilliard, Ohio 43026

Re: K260710
Trade/Device Name: FloShield Air System (FSS-01-1000T - 10mm, 0 Degree FloShield Air, FSS-02-1030T - 10mm, 30 Degree FloShield Air, FSS-03-1045T - 10mm, 45 Degree FloShield Air, FSS-01-0500T - 5mm, 0 Degree FloShield Air, FSS-02-0530T - 5mm, 30 Degree FloShield Air, FSS-01-0545T - 5mm, 45 Degree FloShield Air)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 4, 2026
Received: March 4, 2026

Dear Trudie Seeger:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.06.11 16:31:12 -04'00'

For
Colin Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260710

Please provide the device trade name(s).

FloShield Air System (FSS-01-1000T - 10mm, 0 Degree FloShield Air FSS-02-1030T - 10mm, 30 Degree FloShield Air, FSS-03-1045T - 10mm, 45 Degree FloShield Air, FSS-01-0500T - 5mm, 0 Degree FloShield Air, FSS-02-0530T - 5mm, 30 Degree FloShield Air, FSS-01-0545T - 5mm, 45 Degree FloShield Air)

Please provide your Indications for Use below.

The Air Only FloShield System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging of the lens of a laparoscope and divert surgical debris during minimally-invasive surgery while maintaining visualization of the surgical site.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K260710

510(k) Summary

Prepared on: 2026-06-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FloShield, Inc
Applicant Address	1013 Cactus Rio Drive Weatherford TX 76087 United States
Applicant Contact Telephone	650-823-5559
Applicant Contact	Laird Cagan
Applicant Contact Email	Laird@cmcp.com
Correspondent Name	Advance BioReg, Inc.
Correspondent Address	4170 Bowmansroot Court Hilliard OH 43026 United States
Correspondent Contact Telephone	614-519-1591
Correspondent Contact	Trudie Seeger
Correspondent Contact Email	tseeger@advancebioreg.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FloShield Air System (FSS-01-1000T - 10mm, 0 Degree FloShield Air FSS-02-1030T - 10mm, 30 Degree FloShield Air, FSS-03-1045T - 10mm, 45 Degree FloShield Air, FSS-01-0500T - 5mm, 0 Degree FloShield Air, FSS-02-0530T - 5mm, 30 Degree FloShield Air, FSS-01-0545T - 5mm, 45 Degree FloShield Air)
Common Name	Endoscope lens cleaning and defogging device
Classification Name	Endoscope and Accessories
Regulation Number	21 CRF 876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K080613	Clear-Vu System	OCT

Device Description Summary

21 CFR 807.92(a)(4)

1. Device Description

The FloShield Air System is disposable, gamma irradiated laparoscopic accessory device delivered sterile to the hospital and assembled to the laparoscope prior to surgery. The system requires secondary connections to compressed CO2. The device has two (2) configurations: 1) the 5mm device will accommodate a 5mm laparoscope (outside diameter) of standard length (~31cm) and fit inside a 7mm or 8mm optical trocar (inside diameter) and ; 2) the 10mm device will accommodate a 10mm laparoscope (outside diameter) of standard length (~31mm) and fit inside a 12mm optical trocar (inside diameter).

1.1. Principle of Operation
The Air Only FloShield System consists of a multi-lumen sheath assembly (device) that mounts over the shaft of the laparoscope. A pre-connected tube set connects the device to the existing CO2 insufflation circuit. To prevent fogging, a small portion of CO2 supplied by the interface with the insufflation circuit is redirected through the FloShield device and across the laparoscopic lens, thereby preventing significant accumulation of condensation. Additionally, the continuous flow and velocity of gas across the lens creates a laminar flow or "wind shear," which serves to divert smoke and surgical debris away from the laparoscopic lens during surgery. A portion of the CO2 gas is released through a controlled vent that is provided with the FloShield System (accessory).
1.2. Intended Use
The Air Only FloShield System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging of the lens of a laparoscope and divert surgical debris during minimally-invasive surgery while maintaining visualization of the surgical site.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Air Only FloShield System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging of the lens of a laparoscope and divert surgical debris during minimally-invasive surgery while maintaining visualization of the surgical site.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The FloShield Air System (proposed device) and the Clear-Vu Air System (predicate device: K080613) both are intended to facilitate intraoperative defogging and divert surgical debris of the distal lens of a rigid laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site. Both devices have the same intended use.

Technological Comparison

21 CFR 807.92(a)(6)

Comparison of Technological Characteristics with the Predicate device

Minimally invasive laparoscopic surgery is the technological principle for both the subject and predicate devices. It is based on laparoscopy being used to diagnose and/or treat inside the abdomen as well as other closed spaces. The subject and predicate device facilitate laparoscopy by ensuring the camera lens used to guide the laparoscope remain clear and free of debris. At a high level, the subject and predicate devices as based on the following same technological elements:
• Multi-lumen Sheath Assembly – mounts over shaft of the laparoscopes with 0^0, 30^0 and 45^0 angled tips and protects the camera
• Preconnected Tube Set – connects device to existing CO2 insufflation circuit which is redirected though the device and across the laparoscopic lens to prevent fogging
• Use of insufflator CO2 provides a continuous flow and velocity of gas across the lens creates a laminar flow or "wind shear" which serves to divert smoke and surgical debris
The following technological differences exist between the subject device and predicate devices:
• Use of existing surgical irrigation system (saline) – Predicate
• Use of a Handle Assembly to control the use of CO2 and saline – Predicate
• Use of FloVent (accessory) to allow release of CO2 gas through a controlled vent – Subject device
These technological difference are only related to the removal of the surgical irrigation system from the FloShield Air System and do not impact the intended use nor the safety or effectiveness of the FloShield Air System.
Performance Data
For all the design changes made to the FloShield Air System underwent verification and validation to ensure that the device still meant its Product Specifications. After the manufacturing of the FloShield Air System was transferred to the Tianymed facility in Ningbo, China, some additional design changes were made due to availability of materials and the manufacturing process. The current FloShield Air System has undergone full testing to show that it still meets all of it's specifications (See Performance Testing) as follows:

Biocompatibility Testing
The biocompatibility evaluation of FloShield Air System was conducted in accordance with the Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process," September 2023 as recognized by FDA. The battery of testing included the following tests:
• Chemical Characterization and Toxicological Risk Assessment
• Cytotoxicity
• Sensitization
• Intravenous Reactivity
• Material Mediated Pyrogenicity
• Acute Systemic Toxicity
• Reproductive/development Toxicity
The FloShield Air System body contact is classified as external communicating (tissue/bone/dentin) with a limited duration of contact (≤

24hr).

Functional Testing
• Scope Removal for Defogging/Cleaning
• Air Flush to prevent Fogging
• Devices Provides Vent
• Manifold to Sheath Attachment
• Insertion/Removal into Trocar
• Alignment Guide
Mechanical Testing
• Bond Force
• Insertion Force
• Holding Force
• Mechanical Strength
• Tip Bond Strength

Animal Studies
FloShield has conducted numerous animal studies to verify the initial design of the FloShield System and subsequentially, to verify the performance of design changes and line extension.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance data were provided to support of that the FloShield Air System substantial equivalence determination.

Biocompatibility Testing:
The biocompatibility evaluation of FloShield Air System was conducted in accordance with the Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process," September 2023 as recognized by FDA. The battery of testing included the following tests:
• Cytotoxicity
• Sensitization
• Intravenous Reactivity
• Material Mediated Pyrogenicity
• Acute Systemic Toxicity
• Reproductive/development Toxicity
The FloShield Air System body contact is classified as external communicating (tissue/bone/dentin) with a limited duration of contact (≤ 24hr).

Functional Testing:
• Scope Removal for Defogging/Cleaning
• Air Flush to prevent Fogging
• Devices Provides Vent
• Manifold to Sheath Attachment
• Insertion/Removal into Trocar
• Alignment Guide

Mechanical Testing:
• Bond Force
• Insertion Force
• Holding Force
• Mechanical Strength
• Tip Bond Strength

"Not Applicable"

The biocompatibility, functional and mechanical testing show that the FloShield Air System manufactured by FloShield, Inc. meets all its specifications and performs as well as (equivalent to) its predicate device, Clear-Vu Air System.