October 9, 2025

Boston Scientific
Claire Paddock
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K252910
Trade/Device Name: Orca Air/Water and Suction Valves
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: September 11, 2025
Received: September 12, 2025

Dear Claire Paddock:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

SIVAKAMI VENKATACHALAM -S

for
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

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.	K252910

Please provide the device trade name(s).

Orca Air/Water and Suction Valves

Please provide your Indications for Use below.

The Orca Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI (gastrointestinal) endoscopic procedure.

The Orca Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

I. Submitter

Boston Scientific Corporation

300 Boston Scientific Way

Marlborough, MA 01750

Phone: (508)683-4000

Contact Person: Claire Paddock

Date Prepared: September 11, 2025

II. Device

Trade Name: Orca Air/Water and Suction Valves
Classification Name: Endoscope Channel Accessory
Regulation Number: 876.1500
Product Code: ODC
Classification: Class II

III. Predicate Device

Orca Air/Water and Suction Valves, K160403

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

Orca Air/Water and Suction Valves are endoscopic channel accessories that attach to the Air/Water and Suction ports on the endoscope handle to control the amount of air/water flow and suction of an endoscope.

V. Indications for Use

The Orca Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI (gastrointestinal) endoscopic procedure.

The Orca Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

VI. Comparison of Technological Characteristics with the Predicate Device

Feature	Predicate Device Orca Air/Water Valve, Orca Suction Valve (K160403)	Subject Device Orca Air/Water Valve, Orca Suction Valve	Comparison
Product Code	ODC	ODC	Identical
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Identical
Intended Use	The SmartStart Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The SmartStart Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	The Orca Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure. The Orca Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	Identical
Sterility	Sterile	Sterile	Identical
Sterilization Method	EO	EO	Identical
SAL	10^{-6}	10^{-6}	Identical
Usage	Single Use	Single Use	Identical
Materials	Stainless Steel, ABS Resin, Thermoplastic Elastomers	Polycarbonate, ABS Resin, Thermoplastic Elastomers	Reason for Submission, Substantially Equivalent
Target Population	Patients undergoing an endoscopic procedure	Patients undergoing an endoscopic procedure	Identical
Energy Used / Delivered	None	None	Identical
Method of Application	Manual Actuation	Manual Actuation	Identical
Compatible Endoscopes	Olympus Endoscopes	Olympus and Exalt Endoscopes	Substantially Equivalent Exalt Compatibility Established in K193202
Packaging	Supplied as a kit in Tray sealed in a Tyvek/clear polymer peel pack	Supplied as a kit in Tray with Tyvek Lid	Equivalent

The subject Orca Air/Water and Suction valves have the same mode of operation, intended use, target population, sterility status, and sterilization method, as the predicate devices. The subject devices differ in their material composition, labeled compatibility, and packaging. These differences were evaluated through biocompatibility, packaging, and bench testing, and were found to be equivalent between the subject and predicate devices.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the Orca device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Orca Air/Water and Suction Vales are considered tissue contacting for a duration of less than 24 hours.

Non-Clinical Bench Testing

Air/Water Valve

- Insertion Force
- Removal Force
- Depression Force
- Actuation Time
- Flow Rate
    - Air
    - CO2
    - Water
- Air/Water Leakage
- Seal Pressure Testing
- Operational Life
- Backflow Prevention

Suction Valve:

- Insertion Force
- Removal Force
- Depression Force
- Actuation Time
- Flow Rate
- Operational Life
- Back Pressure

VIII. Conclusions

The Orca Air/Water and Suction Valves have been demonstrated to be substantially equivalent to the predicate devices with respect to indications for use, comparison of technological characteristics with the predicate device, and performance in the specified use conditions. The information submitted within this premarket notification supports the substantially equivalent determination for these devices.