October 2, 2025

Artivion, Inc.
Ms. Karissa Gleason
Senior Regulatory Affairs Specialist
1655 Roberts Blvd, NW
Kennesaw, Georgia 30144

Re: K252059
Trade/Device Name: CryoValve SG Pulmonary Valve
CryoValve SG Pulmonary Valve and Conduit
Regulatory Class: Unclassified
Product Code: OHA
Dated: September 2, 2025
Received: September 2, 2025

Dear Ms. Gleason:

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 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,

Samuel G. Raben -S

Samuel Rabe, Ph.D.
Assistant Director (Acting)
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K252059

Device Name

CryoValve SG Pulmonary Human Heart Valve
CryoValve SG Pulmonary Human Heart Valve and Conduit

Indications for Use *(Describe)*

CryoValve SG Pulmonary Human Heart Valves are indicated for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. They may also be used in the replacement of native pulmonary valves when the Ross Procedure is performed. Pulmonary heart valve allografts are used to repair both congenital and acquired valvular lesions.

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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ARTIVION

510(K) Summary (K252059)
June 30, 2025

Administrative Information:

510(k) Applicant:	Artivion, Inc. 1655 Roberts Blvd., NW Kennesaw, GA 30144 (770) 419-3355
Contact Person:	Karissa Gleason Senior Regulatory Affairs Specialist

Device Name and Classification:

Device Trade Name:	CryoValve® SG Pulmonary Human Heart Valve CryoValve® SG Pulmonary Human Heart Valve and Conduit
Common/Usual Name:	Human Heart Valve
Classification Name:	Allograft Heart Valve
Product Code:	OHA
Regulation Number:	N/A
Device Class:	Unclassified

Intended Use:

CryoValve SG Pulmonary Human Heart Valves are indicated for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. They may also be used in the replacement of native pulmonary valves when the Ross Procedure is performed. Pulmonary heart valve allografts are used to repair both congenital and acquired valvular lesions.

Predicate Devices:

Device	Company	510(k) Number(s), Clearance Date	Product Code
CryoValve® SG Pulmonary Valve CryoValve® SG Pulmonary Valve and Conduit	CryoLife, Inc. 1655 Roberts Blvd., NW Kennesaw, GA 30144	K092021 – May 25, 2010	OHA

Device Description:

The CryoValve SG Pulmonary Human Heart Valve (CryoValve SG) is a human pulmonary heart valve aseptically recovered from donated human tissue from qualified donors. The valve is dissected, treated with an antimicrobial solution, and treated through the SynerGraft® (SG) process to remove the cells and cellular debris that have not already been removed during the postmortem period, harvesting, and the antimicrobial process. The valve is cryopreserved in a tissue culture medium containing cryoprotectants within the innermost pouch of a three-pouch packaging system. The packaging system not only withstands

ultracold temperatures, but also allows for aseptic introduction of the valve into the operating environment. Supercooling by liquid nitrogen boost is begun prior to crystallization to minimize ice crystal damage to the valve matrix. Finally, the valve is transferred to a liquid nitrogen freezer for long-term storage at or below -135°C.

CryoValve SG is distributed in two anatomic configurations: pulmonary valve and conduit, and pulmonary valve.

Implantation of the CryoValve SG Pulmonary Human Heart Valve reduces the risk for induction of HLA class I and class II alloantibodies, based on Panel Reactive Antibody measured at up to one year, compared to the standard processed pulmonary human heart valve. Data have not been provided to evaluate the effect of reduced HLA class I and class II alloantibodies on the long-term durability, or long-term resistance to rejection by the patient, of the CryoValve SG.

Analysis Supporting Substantial Equivalence:

CryoValve SG is substantially equivalent to the predicate CryoValve SG device based on having the same fundamental technology and intended use. The changes between the subject and predicate devices include non-significant changes related to packaging, labeling, transport, tissue and donor testing, equipment, processes, solutions used in device processing, and environmental/personnel monitoring. The safety and performance of CryoValve SG has been evaluated through non-clinical testing. The subject and predicate devices are identical in the following respects:

- Intended Use
- Indications for use
- Technological characteristics/source tissue/material composition
- Processing environment
- Manufacturing process/Proprietary processing steps
- Device packaging configuration and materials
- Donor and tissue eligibility requirements
- Packaging sterilization method
- Aseptic processing and packaging
- Shelf-life of five years

Conclusion:

The subject CryoValve SG device shares the same intended use and technological characteristics as the predicate CryoValve SG devices. The physical, functional and performance specifications for the devices are substantially equivalent. Testing supports that the subject device is as safe and effective as the predicate devices when used according to its labeling.