

K252059 CryoValve SG Pulmonary Valve (SGPV10) CryoValve SG Pulmonary Valve and Conduit (SGPV00)

Oct 2, 2025
93 days to decision

K252059 · Product code: **OHA** · Cardiovascular
Source: <https://www.510kdatabase.net/k252059/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heart Valve, More Than Minimally Manipulated Allograft (OHA)
Date received	Jul 1, 2025
Decision date	Oct 2, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Artivion, Inc.
Location	Kennesaw, GA, US
Contact	Karissa Gleason
Website	http://www.cryolife.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Artivion, Inc. is a biomedical company advancing aortic and cardiovascular technologies. The company operates with a manufacturing facility in Kennesaw, Georgia. Artivion has received FDA 510(k) clearance from total submission. The company specializes in cardiovascular devices, with its regulatory activity spanning 2025. The latest clearance in 2025 demonstrates continued innovation in this critical medical device category. Recent cleared devices include pulmonary valve and conduit systems designed for surgical cardiovascular applications. These products reflect the compa...