

**K092021 CRYOVALVE SG PULMONARY HUMAN HEART VALVE
(AND CONDUIT)**May 25, 2010
323 days to decisionK092021 · Product code: **OHA** · Cardiovascular
Source: <https://www.510kdatabase.net/k092021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heart Valve, More Than Minimally Manipulated Allograft (OHA)
Date received	Jul 6, 2009
Decision date	May 25, 2010
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cryolife, Inc.
Location	Kennesaw, GA, US
Contact	JOHN D FERROS
510(k) history	12 submissions · 12 cleared · 2006-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026