

K183635 PhotoFix Decellularized Bovine PericardiumFeb 14, 2019
50 days to decisionK183635 · Product code: **PSQ** · CardiovascularSource: <https://www.510kdatabase.net/k183635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intracardiac Patch Or Pledget, Biologically Derived (PSQ)
Date received	Dec 26, 2018
Decision date	Feb 14, 2019
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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