FDA 510(k) Premarket Notification

CLEARED

K210331 CardiaMend Pericardial and Epicardial Reconstruction Matrix

Dec 21, 2021
319 days to decision

K210331 · Product code: **PSQ** · Cardiovascular
Source: https://www.510kdatabase.net/k210331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intracardiac Patch Or Pledget, Biologically Derived (PSQ)
Date received	Feb 5, 2021
Decision date	Dec 21, 2021
Days to decision	319 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Helios Cardio, Inc.**
Location	Weston, MA, US
Contact	Yiannis Monovoukas
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**QUARAS, LLC**
Contact	Roshana Ahmed

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210331/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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