

K252445 Fusion Bioline Vascular GraftApr 27, 2026
266 days to decisionK252445 · Product code: **DSY** · CardiovascularSource: <https://www.510kdatabase.net/k252445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Aug 4, 2025
Decision date	Apr 27, 2026
Days to decision	266 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maquet Cardiovascular, LLC
Location	San Jose, CA, US
Contact	Suwah Amara
510(k) history	14 submissions · 14 cleared · 2008-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252445/>; 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 May 13, 2026