

K251375 PuraCath Firefly Needleless Connector IT (9005)Feb 12, 2026
286 days to decisionK251375 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k251375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 2, 2025
Decision date	Feb 12, 2026
Days to decision	286 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Puracath Medical, Inc.
Location	Newark, CA, US
Contact	Julia Rasooly
510(k) history	3 submissions · 3 cleared · 2016-2026

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