

K180546 Jet Power Injectable PICCNov 21, 2018
265 days to decisionK180546 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k180546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Mar 1, 2018
Decision date	Nov 21, 2018
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jet Medical, Inc.
Location	Schwenksville, PA, US
Contact	Courtney Nix
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Medcomp (Dba Medical Components, Inc.)
Contact	Courtney Nix

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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