

K191362 LifeFlow Blood SystemMay 20, 2020
364 days to decisionK191362 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k191362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 22, 2019
Decision date	May 20, 2020
Days to decision	364 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	410 Medical, Inc.
Location	Durham, NC, US
Contact	Galen Robertson
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Danielle Besal

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191362/> 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 June 28, 2026