

K181269 iCertaintyDec 14, 2018
214 days to decisionK181269 · Product code: **DPW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	May 14, 2018
Decision date	Dec 14, 2018
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rfpi
Location	Greenville, NC, US
Contact	Jeffery Basham
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Edgeone Medical
Contact	Jerzy Wojcik

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/k181269/> 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