FDA 510(k) Premarket Notification

K181269 iCertainty

CLEARED

Dec 14, 2018
214 days to decision

K181269 · Product code: **DPW** · General & Plastic Surgery
Source: 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