

K201114 Bidop 7Jan 5, 2021
253 days to decisionK201114 · Product code: **DPW** · Cardiovascular
Source: <https://www.510kdatabase.net/k201114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Apr 27, 2020
Decision date	Jan 5, 2021
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Koven Technology, Inc.
Location	St. Louis, MO, US
Contact	Heather Bell
510(k) history	18 submissions · 18 cleared · 1994-2021

REGULATORY CONSULTANT

Consulting firm	Delphi Consulting Group
Contact	Harvey Knauss

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

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