FDA 510(k) Premarket Notification

K201114 Bidop 7

CLEARED

Jan 5, 2021
253 days to decision

K201114 · 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