FDA 510(k) Premarket Notification

K920333 SMARTDOP 20 BI-DIRECTIONAL BLOOD FLOW DETECTOR

CLEARED

Jan 22, 1993
361 days to decision

K920333 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k920333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Jan 27, 1992
Decision date	Jan 22, 1993
Days to decision	361 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Koven and Assoc., Inc.**
Location	St. Louis, MO, US
Contact	PAUL KOVEN
510(k) history	8 submissions · 8 cleared · 1989-1993