FDA 510(k) Premarket Notification

K013376 QFLOW 500 PERFUSION MONITORING SYSTEM

CLEARED

May 8, 2002
209 days to decision

K013376 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k013376/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Oct 11, 2001
Decision date	May 8, 2002
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hemedex Incorporated**
Location	Hopkonton, MA, US
Contact	DEBBIE IAMPIETRO
510(k) history	4 submissions · 4 cleared · 2002-2014