FDA 510(k) Premarket Notification

K823342 PERCOR INTRA-AORTIC BALLOON INSERTION

CLEARED

Jan 24, 1983
77 days to decision

K823342 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k823342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Nov 8, 1982
Decision date	Jan 24, 1983
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**Datascope Corp.**
Location	Mchenry, IL, US
510(k) history	136 submissions · 135 cleared · 1976-2019