FDA 510(k) Premarket Notification

K974178 PASSPORT 5L-CE MODEL 0998-00-0131XXX

CLEARED

Jun 26, 1998
232 days to decision

K974178 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k974178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Nov 6, 1997
Decision date	Jun 26, 1998
Days to decision	232 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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