FDA 510(k) Premarket Notification

K843533 CARDIAC EVENT RECORDER

CLEARED

Jun 28, 1985
294 days to decision

K843533 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k843533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Sep 7, 1984
Decision date	Jun 28, 1985
Days to decision	294 days
Third-party review	No

APPLICANT

Company	**Cryo2 Corp.**
Location	Walker, MI, US
510(k) history	2 submissions · 2 cleared · 1984-1985