FDA 510(k) Premarket Notification

K811425 CARDIACMONITORS

CLEARED

Sep 16, 1981
117 days to decision

K811425 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k811425/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	May 22, 1981
Decision date	Sep 16, 1981
Days to decision	117 days
Third-party review	No

APPLICANT

Company	**Pulse Time Products, Ltd.**
Location	Walker, MI, US
510(k) history	6 submissions · 6 cleared · 1981-1990