FDA 510(k) Premarket Notification

K961138 ESORT II + 400 SERIES MONITOR

CLEARED

Dec 10, 1996
264 days to decision

K961138 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k961138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Mar 21, 1996
Decision date	Dec 10, 1996
Days to decision	264 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medical Data Electronics**
Location	Arleta, CA, US
Contact	DAVID M TRUBLOOD
510(k) history	27 submissions · 27 cleared · 1985-2002