FDA 510(k) Premarket Notification

CLEARED

K000660 ESCORT II+ 400 SERIES (ESCORT PRISM), MODEL 20400, 20401, 20403, MONITOR, MODELS 20411, 20412, 20413

Mar 28, 2000
29 days to decision

K000660 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k000660/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Feb 28, 2000
Decision date	Mar 28, 2000
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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