FDA 510(k) Premarket Notification

K820399 HS20 PORT. OPERATING ROOM MONITOR

CLEARED

Mar 22, 1982
39 days to decision

K820399 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k820399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Feb 11, 1982
Decision date	Mar 22, 1982
Days to decision	39 days
Third-party review	No

APPLICANT

Company	**Medtel Pty. , Ltd.**
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1979-1983