FDA 510(k) Premarket Notification

K802357 TELEMETRY PACEMAKER MONITOR

CLEARED

Feb 12, 1981
139 days to decision

K802357 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k802357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Sep 26, 1980
Decision date	Feb 12, 1981
Days to decision	139 days
Third-party review	No

APPLICANT

Company	**Intermedics, Inc.**
Location	Mchenry, IL, US
510(k) history	211 submissions · 201 cleared · 1977-1996