FDA 510(k) Premarket Notification

K801339 TELEMETRY DECODER

CLEARED

Sep 23, 1981
476 days to decision

K801339 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k801339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 4, 1980
Decision date	Sep 23, 1981
Days to decision	476 days
Third-party review	No

APPLICANT

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