FDA 510(k) Premarket Notification

K801338 CYBERLITH PROGRAMMER

CLEARED

Jan 7, 1981
217 days to decision

K801338 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k801338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 4, 1980
Decision date	Jan 7, 1981
Days to decision	217 days
Third-party review	No

APPLICANT

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