FDA 510(k) Premarket Notification

K810385 CYBERLITH I PULSE GENERATOR MODEL 253-04

CLEARED

Apr 1, 1981
47 days to decision

K810385 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k810385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Feb 13, 1981
Decision date	Apr 1, 1981
Days to decision	47 days
Third-party review	No

APPLICANT

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