FDA 510(k) Premarket Notification

K802293 POLYFLEX IMPLANTABLE PACING LEAD

CLEARED

Oct 31, 1980
42 days to decision

K802293 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k802293/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Sep 19, 1980
Decision date	Oct 31, 1980
Days to decision	42 days
Third-party review	No

APPLICANT

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