FDA 510(k) Premarket Notification

K790101 ISOLATION SLEEVE, MODEL 346-01

CLEARED

Jan 24, 1979
8 days to decision

K790101 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k790101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 16, 1979
Decision date	Jan 24, 1979
Days to decision	8 days
Third-party review	No

APPLICANT

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