FDA 510(k) Premarket Notification

K821073 PULSE GENERATOR

CLEARED

May 7, 1982
21 days to decision

K821073 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k821073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Apr 16, 1982
Decision date	May 7, 1982
Days to decision	21 days
Third-party review	No

APPLICANT

Company	**Biotronik Sales, Inc.**
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1980-1988