FDA 510(k) Premarket Notification

K830862 NEDS-01 & EPR-500

CLEARED

May 25, 1983
68 days to decision

K830862 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k830862/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Mar 18, 1983
Decision date	May 25, 1983
Days to decision	68 days
Third-party review	No

APPLICANT

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