FDA 510(k) Premarket Notification

K860036 EDP-20 PACEMAKER

CLEARED

Jan 12, 1987
371 days to decision

K860036 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k860036/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jan 6, 1986
Decision date	Jan 12, 1987
Days to decision	371 days
Third-party review	No

APPLICANT

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