FDA 510(k) Premarket Notification

K802028 IMPLANTABLE VENTRICULAR-INHIB. C.P. GEN

CLEARED

Sep 26, 1980
36 days to decision

K802028 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k802028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 21, 1980
Decision date	Sep 26, 1980
Days to decision	36 days
Third-party review	No

APPLICANT

Company	**Telectronics, Inc.**
Location	Mchenry, IL, US
510(k) history	107 submissions · 107 cleared · 1977-1990