FDA 510(k) Premarket Notification

K831771 IMPLANTABLE PROGRAM. CARDIAC PULSE GEN

CLEARED

Aug 16, 1983
75 days to decision

K831771 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k831771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 2, 1983
Decision date	Aug 16, 1983
Days to decision	75 days
Third-party review	No

APPLICANT

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