

K853206 IMPLANT PROGRAM CARDIAC PULSE GEN W/MOD SET SCREW

Sep 12, 1985
43 days to decision

K853206 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k853206/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 31, 1985
Decision date	Sep 12, 1985
Days to decision	43 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k853206/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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