FDA 510(k) Premarket Notification

K953417 MINIFLEX MODEL 340, 341, AND 342 PULSE GENERATORS

CLEARED

Sep 29, 1995
113 days to decision

K953417 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k953417/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jun 8, 1995
Decision date	Sep 29, 1995
Days to decision	113 days
Third-party review	No

APPLICANT

Company	**Cook Pacemaker Corp.**
Location	Mchenry, IL, US
Contact	RICHYARD E SHIREY
510(k) history	34 submissions · 31 cleared · 1981-1997