FDA 510(k) Premarket Notification

K954092 ALTERNATE STERLIZATION PROCESS & MODIFIED DF-1 LEAD CONNECTOR (MODIFICATION)

CLEARED

Dec 15, 1995
127 days to decision

K954092 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k954092/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 10, 1995
Decision date	Dec 15, 1995
Days to decision	127 days
Third-party review	No

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	DENNIS CONNOLLY
510(k) history	475 submissions · 453 cleared · 1977-2023