FDA 510(k) Premarket Notification

K811350 UNIPOLAR SPECTRAX IMPL. PULSE GENERAT.

CLEARED

Jul 1, 1981
49 days to decision

K811350 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k811350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	May 13, 1981
Decision date	Jul 1, 1981
Days to decision	49 days
Third-party review	No

APPLICANT

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