FDA 510(k) Premarket Notification

K812153 MEDTRONIC SPECTRAX

CLEARED

Aug 31, 1981
33 days to decision

K812153 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k812153/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Jul 29, 1981
Decision date	Aug 31, 1981
Days to decision	33 days
Third-party review	No

APPLICANT

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