FDA 510(k) Premarket Notification

K803313 PACING SYSTEM ANALYZER

CLEARED

Feb 23, 1981
54 days to decision

K803313 · Product code: **DTE** · Cardiovascular
Source: https://www.510kdatabase.net/k803313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse-generator, Pacemaker, External (DTE)
Date received	Dec 31, 1980
Decision date	Feb 23, 1981
Days to decision	54 days
Third-party review	No

APPLICANT

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