FDA 510(k) Premarket Notification

K780621 LEAD, PACING, ATRIAL, ENDOCARDIAL, TINED

CLEARED

Jul 26, 1978
103 days to decision

K780621 · Product code: **DTB** · Cardiovascular
Source: https://www.510kdatabase.net/k780621/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Permanent Pacemaker Electrode (DTB)
Date received	Apr 14, 1978
Decision date	Jul 26, 1978
Days to decision	103 days
Third-party review	No

APPLICANT

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