FDA 510(k) Premarket Notification

K032926 EKG SPEAKS

CLEARED

Oct 15, 2003
23 days to decision

K032926 · Product code: **KRE** · Cardiovascular
Source: https://www.510kdatabase.net/k032926/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Pacemaker Generator Function, Indirect (KRE)
Date received	Sep 22, 2003
Decision date	Oct 15, 2003
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k032926/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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