FDA 510(k) Premarket Notification

K852469 SAF-D-FIB

CLEARED

Sep 16, 1985
95 days to decision

K852469 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k852469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jun 13, 1985
Decision date	Sep 16, 1985
Days to decision	95 days
Third-party review	No

APPLICANT

Company	**Medtronic Andover Medical, Inc.**
Location	Lowell, MA, US
Contact	EDWARD SHAUGHNESSY
510(k) history	6 submissions · 6 cleared · 1985-1991