FDA 510(k) Premarket Notification

K030856 ER800 SERIES ECG EVENT RECORDER

CLEARED

Mar 28, 2003
10 days to decision

K030856 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k030856/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Mar 18, 2003
Decision date	Mar 28, 2003
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Braemar Corp.**
Location	Burnsville, MN, US
Contact	DAVID NORBERG
510(k) history	5 submissions · 5 cleared · 1995-2003