FDA 510(k) Premarket Notification

CLEARED

K071011 MODIFICATION TO: BRAEMAR ER900 SERIES ENHANCED ALGORITHM ECG EVENT RECORDER

Apr 27, 2007
17 days to decision

K071011 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k071011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Apr 10, 2007
Decision date	Apr 27, 2007
Days to decision	17 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Braemar, Inc.**
Location	Burnsville, MN, US
Contact	DARREN DERSHEM
510(k) history	5 submissions · 5 cleared · 2004-2008