K081444 BRAEMAR FUSION WIRELESS - AMBULATORY ECG ARRHYTHMIA MONITORING SYSTEM

CLEARED

Jul 31, 2008
70 days to decision

K081444 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k081444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	May 22, 2008
Decision date	Jul 31, 2008
Days to decision	70 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