K131044 SENSICARDIAC MOBI DIAGNOSTIC HEART MURMUR APPLICATION

CLEARED

Sep 4, 2013
142 days to decision

K131044 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k131044/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Apr 15, 2013
Decision date	Sep 4, 2013
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diacoustic Medical Devices (Pty) , Ltd.**
Location	Crofton, MD, US
Contact	YOLANDA SMITH
510(k) history	2 submissions · 2 cleared · 2011-2013