FDA 510(k) Premarket Notification

K132206 MELYS ATRIAL FIBRILLATION SCREENING MONITOR

CLEARED

Mar 19, 2014
246 days to decision

K132206 · Product code: **DXH** · Cardiovascular
Source: https://www.510kdatabase.net/k132206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Jul 16, 2013
Decision date	Mar 19, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Advanced Fluidics, LLC**
Location	Crofton, MD, US
Contact	E J SMITH
510(k) history	1 submissions · 1 cleared · 2014-2014