

K132206 MELYS ATRIAL FIBRILLATION SCREENING MONITORMar 19, 2014
246 days to decisionK132206 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132206/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 7, 2026