

**K153275 Aingeal Activity System**Feb 26, 2016  
106 days to decisionK153275 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153275/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 12, 2015
Decision date	Feb 26, 2016
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intelesens, Ltd.</b>
Location	Belfast, GB
Contact	Patricia Pepper
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153275/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 3, 2026