

**K103242 REDSENSE-ALARM UNIT AND SENSOR**Feb 10, 2011  
100 days to decisionK103242 · Product code: **ODX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k103242/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autonomous Extracorporeal Blood Leak Detector/alarm (ODX)
Date received	Nov 2, 2010
Decision date	Feb 10, 2011
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Redsense Medical AB</b>
Location	Findley, MN, US
Contact	CONSTANCE G BUNDY
510(k) history	4 submissions · 4 cleared · 2007-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103242/> 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 8, 2026