

K071013 REDSENSEOct 18, 2007
191 days to decisionK071013 · Product code: **ODX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k071013/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autonomous Extracorporeal Blood Leak Detector/alarm (ODX)
Date received	Apr 10, 2007
Decision date	Oct 18, 2007
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071013/> 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 8, 2026