

K092955 REDSENSE-HOME USEMay 10, 2010
227 days to decisionK092955 · Product code: **ODX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k092955/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autonomous Extracorporeal Blood Leak Detector/alarm (ODX)
Date received	Sep 25, 2009
Decision date	May 10, 2010
Days to decision	227 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

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