FDA 510(k) Premarket Notification

K130554 REDSENSE ALARM SYSTEM

CLEARED

Nov 22, 2013
263 days to decision

K130554 · Product code: **ODX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k130554/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autonomous Extracorporeal Blood Leak Detector/alarm (ODX)
Date received	Mar 4, 2013
Decision date	Nov 22, 2013
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Redsense Medical AB**
Location	Findley, MN, US
Contact	PATRIK BYHMER
510(k) history	4 submissions · 4 cleared · 2007-2013