

K123563 LEADCARE (R) ULTRA (TM) BLOOD LEAD TESTING SYSTEMAug 20, 2013
274 days to decisionK123563 · Product code: **DOF** · Chemistry
Source: <https://www.510kdatabase.net/k123563/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lead, Atomic Absorption (DOF)
Date received	Nov 19, 2012
Decision date	Aug 20, 2013
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Magellan Diagnostics
Location	North Billerica, MA, US
Contact	STUART NAYLOR
510(k) history	2 submissions · 2 cleared · 2013-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123563/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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