

**K133512 LOCI VITAMIN B12 (VB12) FLEX REAGENT  
CARTRIDGE, LOCI ANEMIA CALIBRATOR (ANEM CAL)**Jan 2, 2014  
48 days to decisionK133512 · Product code: **CDD** · Chemistry  
Source: <https://www.510kdatabase.net/k133512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Nov 15, 2013
Decision date	Jan 2, 2014
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	ANNA MARIE K ENNIS
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133512/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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