

K093631 B12 REAGENT CARTRIDGE AND FOL FLEX REAGENT CARTRIDGE, MODEL RF642 AND RF644

Feb 12, 2010
80 days to decision

K093631 · Product code: **CDD** · Chemistry
Source: <https://www.510kdatabase.net/k093631/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Nov 24, 2009
Decision date	Feb 12, 2010
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k093631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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