

**K060755 ELECSYS VITAMIN B12 IMMUNOASSAY, CALSET II
AND CALCHECK**Apr 10, 2006
20 days to decisionK060755 · Product code: **CDD** · Chemistry
Source: <https://www.510kdatabase.net/k060755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Mar 21, 2006
Decision date	Apr 10, 2006
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	RANDY J JOHNSON
510(k) history	264 submissions · 263 cleared · 1999-2013

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