

**K051297 ELECSYS N-MID OSTEOCALCIN, ELECSYS
OSTEOCALCIN CALSET, ELECSYS OSTEOCALCIN CALCHECK**Sep 8, 2005
113 days to decisionK051297 · Product code: **NEO** · Chemistry
Source: <https://www.510kdatabase.net/k051297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Osteocalcin (NEO)
Date received	May 18, 2005
Decision date	Sep 8, 2005
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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