

K000534 COBAS INTEGRA REAGENT CASSETTE FOR RHEUMATOID FACTOR IIApr 5, 2000
48 days to decisionK000534 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k000534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Feb 17, 2000
Decision date	Apr 5, 2000
Days to decision	48 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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