

K982382 COBAS INTEGRA REAGENT CASSETTESSep 28, 1998
82 days to decisionK982382 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k982382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jul 8, 1998
Decision date	Sep 28, 1998
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982382/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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