

K001468 ELECSYS CA 15-3 TEST SYSTEMOct 23, 2000
166 days to decisionK001468 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k001468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	May 10, 2000
Decision date	Oct 23, 2000
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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