

K010588 ELECSYSCA 15-3 II ASSAYMar 28, 2001
29 days to decisionK010588 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k010588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Feb 27, 2001
Decision date	Mar 28, 2001
Days to decision	29 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026