

K910553 ROCHE APOLIPOPROTEIN STANDARDMay 8, 1991
90 days to decisionK910553 · Product code: **DER** · Immunology
Source: <https://www.510kdatabase.net/k910553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER)
Date received	Feb 7, 1991
Decision date	May 8, 1991
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k910553/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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