

K942908 IGM RF EIAJan 20, 1995
213 days to decisionK942908 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k942908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Jun 21, 1994
Decision date	Jan 20, 1995
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	JOSEPH BOHN
510(k) history	164 submissions · 164 cleared · 1984-2002

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