

K941398 EL-RF/3 (IGM-IGG-IGA) KITJul 28, 1995
493 days to decisionK941398 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k941398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Mar 22, 1994
Decision date	Jul 28, 1995
Days to decision	493 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Theratest Laboratories, Inc.
Location	Chicago, IL, US
Contact	CHRISTOPHER J FROELICH,MD
510(k) history	22 submissions · 22 cleared · 1991-2010

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