

K970373 RAICHEM RHEUMATOID FACTOR SPIAApr 17, 1997
73 days to decisionK970373 · Product code: **DHR** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Feb 3, 1997
Decision date	Apr 17, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Henage Diagnostics, Inc.
Location	Waltham, MA, US
Contact	JOSEPH M CALLIFABO
510(k) history	1 submissions · 1 cleared · 1997-1997

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