

K920753 RF STAT IGM TEST KITMar 30, 1992
40 days to decisionK920753 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k920753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Feb 19, 1992
Decision date	Mar 30, 1992
Days to decision	40 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biowittaker Molecular Applications, Inc.
Location	Walkersville, MD, US
Contact	LEIF E OLSEN
510(k) history	10 submissions · 10 cleared · 1992-1996

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