

K971379 TINAQUANT RHEUMATOID FACTOR ASSAYJun 17, 1997
64 days to decisionK971379 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k971379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Apr 14, 1997
Decision date	Jun 17, 1997
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	Yvette Lloyd
510(k) history	340 submissions · 340 cleared · 1976-1999

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