

K871196 RHEUMA-CHECK ENZYME IMMUNOASSAY TESTMay 6, 1987
43 days to decisionK871196 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k871196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Mar 24, 1987
Decision date	May 6, 1987
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Orion Diagnostica, Inc.
Location	Mchenry, IL, US
Contact	JULIE DEMARCO
510(k) history	28 submissions · 28 cleared · 1980-1994

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