

K040200 MESACUP-2 TEST CENP-BMar 4, 2004
35 days to decisionK040200 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k040200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jan 29, 2004
Decision date	Mar 4, 2004
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rhigene, Inc.
Location	Des Plaines, IL, US
Contact	YUSUKE KOBE
510(k) history	15 submissions · 15 cleared · 2000-2004

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