

**K031308 RHIGENE MESACUP-2 ANTI-MITOCHONDRIA M2
TEST, MODEL 10760**Sep 26, 2003
155 days to decisionK031308 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k031308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Apr 24, 2003
Decision date	Sep 26, 2003
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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