

K030238 BINDAZYME ANTI-MITOCHONDRIA M2 IGGAM EIA KITMar 24, 2003
60 days to decisionK030238 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k030238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Jan 23, 2003
Decision date	Mar 24, 2003
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site, Ltd.
Location	Los Angeles, CA, US
Contact	JAY H GELLER
510(k) history	115 submissions · 115 cleared · 1988-2024

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