

**K982121 ENZYMATIC MITOCHONDRIAL ANTIBODY (M2)
REAGENT**Sep 17, 1998
93 days to decisionK982121 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k982121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Jun 16, 1998
Decision date	Sep 17, 1998
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trace Scientific , Ltd.
Location	Clayton, Vic 3168, AU
Contact	David Johnston
510(k) history	55 submissions · 55 cleared · 1986-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982121/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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