

K092736 EUROIMMUN ANTI-M2-3E ELISA (IGG)Sep 2, 2010
363 days to decisionK092736 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k092736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Sep 4, 2009
Decision date	Sep 2, 2010
Days to decision	363 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Euroimmun Us, Inc.
Location	Morristown, NJ, US
Contact	KATHRYN KOHL
510(k) history	19 submissions · 19 cleared · 2009-2020

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