

K141375 ELIA M2Feb 13, 2015
262 days to decisionK141375 · Product code: **DBM** · Immunology
Source: <https://www.510kdatabase.net/k141375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	May 27, 2014
Decision date	Feb 13, 2015
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary
Other names	IMMUNOASSAY, POSITIVE CONTROL 100, POSITIVE CONTROL 250

APPLICANT

Company	Phadia US, Inc.
Location	Portae, MI, US
Contact	MANUELA CONSTANZE HOG
510(k) history	22 submissions · 21 cleared · 2006-2015

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