

K083381 EUROIMMUN ANTI-DSDNA-NCX ELISA (IGG)Apr 15, 2009
152 days to decisionK083381 · Product code: **LRM** · Immunology
Source: <https://www.510kdatabase.net/k083381/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Nov 14, 2008
Decision date	Apr 15, 2009
Days to decision	152 days
Third-party review	No
Summary / Statement	Statement

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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