

K183313 EUROIMMUN Anti-tissue Transglutaminase ELISA (IgA), EUROIMMUN Anti-tissue Transglutaminase ELISA (IgG)

Feb 28, 2019
91 days to decision

K183313 · Product code: **MVM** · Immunology
Source: <https://www.510kdatabase.net/k183313/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Endomysial(tissue Transglutaminase) (MVM)
Date received	Nov 29, 2018
Decision date	Feb 28, 2019
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183313/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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