

**K083850 EUROIMMUN ANCA IFA EUROPLUS GRANULOCYTE
BIOCHIP MOSAIC TEST SYSTEMS**

May 20, 2009
147 days to decision

K083850 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k083850/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Dec 24, 2008
Decision date	May 20, 2009
Days to decision	147 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083850/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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