

**K051489 EUROIMMUN ANCA IFA GRANULOCYTE BIOCHIP
MOSCAIC IGG ANTIBODY IN HUMAN SERUM**Feb 16, 2006
255 days to decisionK051489 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k051489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jun 6, 2005
Decision date	Feb 16, 2006
Days to decision	255 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Euroimmun Us, LLC
Location	Boonton Twp, NJ, US
Contact	KATHRYN KOHL
510(k) history	6 submissions · 6 cleared · 2006-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k051489/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 26, 2026