

**K060700 EUROIMMUN PR3 ELISA KIT. EUROIMMUN MPO
ELISA KIT.**Sep 8, 2006
177 days to decisionK060700 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k060700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Mar 15, 2006
Decision date	Sep 8, 2006
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

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/k060700/>; 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