FDA 510(k) Premarket Notification

K082130 EUROIMMUN ANTI-PR3-HN-HR ELISA (IGG)

CLEARED

Apr 7, 2009
252 days to decision

K082130 · Product code: **MOB** · Immunology
Source: https://www.510kdatabase.net/k082130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jul 29, 2008
Decision date	Apr 7, 2009
Days to decision	252 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/k082130/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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