

K061376 EL-ANCA: ANTI-MPO, ANTI-PR3, ANTI-MPO AND ANTI-PR3Jul 20, 2006
64 days to decisionK061376 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k061376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	May 17, 2006
Decision date	Jul 20, 2006
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Theratest Laboratories, Inc.
Location	Chicago, IL, US
Contact	MARIUS TEODORESCU, MD, PH.D.
510(k) history	22 submissions · 22 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061376/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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