

K974701 ORGENTEC ANTI-MPO (P-ANCA) ELISAFeb 17, 1998
71 days to decisionK974701 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k974701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Dec 8, 1997
Decision date	Feb 17, 1998
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	American Laboratory Products Co., Ltd.
Location	Windham, NH, US
Contact	RICHARD CONLEY
510(k) history	27 submissions · 27 cleared · 1991-2002

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