

K943630 DIASTAT ANTI-MPO (PANCA) KITMar 6, 1995
223 days to decisionK943630 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k943630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jul 26, 1994
Decision date	Mar 6, 1995
Days to decision	223 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shield Diagnostics, Ltd.
Location	Scotland, KN
Contact	PETER FOSTER
510(k) history	27 submissions · 27 cleared · 1990-2000

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