

K942813 DIASTAT ANTI-PR3 (C-ANCA) KITMar 6, 1995
265 days to decisionK942813 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k942813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jun 14, 1994
Decision date	Mar 6, 1995
Days to decision	265 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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