

**K954105 EIA KIT FOR THE DETCTION OF ANTI-PR3
ANTIBODIES**Mar 19, 1996
201 days to decisionK954105 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k954105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Aug 31, 1995
Decision date	Mar 19, 1996
Days to decision	201 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scimedx Corp.
Location	Denvill, NJ, US
Contact	THOMAS BRITTEN
510(k) history	14 submissions · 14 cleared · 1996-2001

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