

K010289 SCIMEDX PHASE II MPO IGG ANTIBODY EIAMar 7, 2001
35 days to decisionK010289 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k010289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jan 31, 2001
Decision date	Mar 7, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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