

K962360 IFA KIT FOR THE DETECTION OF C-ANCA ANTIBODIESSep 30, 1996
103 days to decisionK962360 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k962360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jun 19, 1996
Decision date	Sep 30, 1996
Days to decision	103 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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