

K092601 IMMULISA ANCA SCREEN ELISAOct 7, 2010
409 days to decisionK092601 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k092601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Aug 24, 2009
Decision date	Oct 7, 2010
Days to decision	409 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Immco Diagnostics, Inc.
Location	Buffalo, NY, US
Contact	KEVIN LAWSON
510(k) history	55 submissions · 55 cleared · 1988-2018

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