

K983390 IS-ANTI-MPO IGG ELISA TEST SYSTEMNov 18, 1998
54 days to decisionK983390 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k983390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Sep 25, 1998
Decision date	Nov 18, 1998
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Columbia Bioscience, Inc.
Location	Frederick, MD, US
Contact	NORMAN JENKINS
510(k) history	13 submissions · 13 cleared · 1996-1999

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