

**K243776 Anti-Neutrophil Cytoplasmic Antibodies (Ethanol-Fixed)**May 7, 2025  
149 days to decisionK243776 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k243776/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Dec 9, 2024
Decision date	May 7, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Anti-Neutrophil Cytoplasmic Antibodies (Formalin-Fixed)

**APPLICANT**

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Company	<b>Zeus Scientific</b>
Location	Branchburg, NJ, US
Contact	Mark Kohnitsky
510(k) history	5 submissions · 5 cleared · 2023-2025

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