

**K220763 ALPCO Calprotectin Immunoturbidimetric Assay**Apr 13, 2023  
393 days to decisionK220763 · Product code: **NXO** · Immunology  
Source: <https://www.510kdatabase.net/k220763/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calprotectin, Fecal (NXO)
Date received	Mar 16, 2022
Decision date	Apr 13, 2023
Days to decision	393 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>ALPCO</b>
Location	Salem, NH, US
Contact	Chris Wisherd
510(k) history	2 submissions · 2 cleared · 2019-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Diazyme Laboratories, Inc.</b>
Contact	Abhijit Datta

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220763/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026