

**K181012 BUHLMANN fCAL ELISA**Jun 4, 2018  
48 days to decisionK181012 · Product code: **NXO** · Immunology  
Source: <https://www.510kdatabase.net/k181012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calprotectin, Fecal (NXO)
Date received	Apr 17, 2018
Decision date	Jun 4, 2018
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Buhlmann Laboratories AG</b>
Location	Windham, NH, US
Contact	Alicja Ritz
510(k) history	4 submissions · 4 cleared · 1995-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mapi Srs, an Icon Plc Company</b>
Contact	Roshana Ahmed

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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