

**K191718 Buhlmann fCAL turbo and CALEX Cap**Sep 24, 2019  
90 days to decisionK191718 · Product code: **NXO** · Immunology  
Source: <https://www.510kdatabase.net/k191718/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calprotectin, Fecal (NXO)
Date received	Jun 26, 2019
Decision date	Sep 24, 2019
Days to decision	90 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	Laura Zurbrugg
510(k) history	4 submissions · 4 cleared · 1995-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>QUARAS, LLC</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/k191718/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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