

**K232057 BÜHLMANN fCAL® turbo and CALEX® Cap**Feb 6, 2024  
210 days to decisionK232057 · Product code: **NXO** · Immunology  
Source: <https://www.510kdatabase.net/k232057/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calprotectin, Fecal (NXO)
Date received	Jul 11, 2023
Decision date	Feb 6, 2024
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>B?hlmann Laboratories AG</b>
Location	Sch?nenbuch, CH
Contact	Laura Zurbrugg
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>QUARAS, LLC</b>
Contact	Roshana Ahmed, M.A., RAC

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/k232057/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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