

K190784 BUHLMANN fCAL turboJun 25, 2019
90 days to decisionK190784 · Product code: **NXO** · Immunology
Source: <https://www.510kdatabase.net/k190784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calprotectin, Fecal (NXO)
Date received	Mar 27, 2019
Decision date	Jun 25, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Buhlmann Laboratories AG
Location	Windham, NH, US
Contact	Laura Zurbrugg
510(k) history	4 submissions · 4 cleared · 1995-2019

REGULATORY CONSULTANT

Consulting firm	QUARAS, LLC
Contact	Roshana Ahmed

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190784/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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