February 6, 2024

BÜHLMANN Laboratories AG
% Roshana Ahmed, M.A., RAC
President
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: K232057
Trade/Device Name: BÜHLMANN fCAL turbo and CALEX Cap
Regulation Number: 21 CFR 866.5180
Regulation Name: Fecal calprotectin immunological test system
Regulatory Class: Class II
Product Code: NXO
Dated: January 29, 2024
Received: January 29, 2024

Dear Roshana Ahmed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232057

Device Name

BÜHLMANN fCAL® turbo and CALEX® Cap

Indications for Use *(Describe)*

The BÜHLMANN fCAL® turbo is an in vitro diagnostic assay intended for the quantitative measurement of fecal calprotectin, a neutrophilic protein that is a marker of intestinal mucosal inflammation, in human stool. The BÜHLMANN fCAL® turbo aids in the diagnosis of inflammatory bowel disease (IBD), specifically Crohn's disease (CD) and ulcerative colitis (UC) and aids in the differentiation of IBD from irritable bowel syndrome (IBS) in conjunction with other laboratory and clinical findings.

The BÜHLMANN CALEX® Cap is a single use tube intended for the preparation of human stool samples to be used with the BÜHLMANN fCAL® turbo.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

BÜHLMANN Laboratories AG
Baselstrasse 55
Schönenbuch CH-4124
Switzerland
Phone: +41 61 487 12 50

Contact Person: Michael Schneider
Date Prepared: February 5, 2024

II. Device

Device Proprietary Name:	BÜHLMANN fCAL® turbo, CALEX® Cap
Common or Usual Name:	Fecal calprotectin immunological test system
Classification Name:	Calprotectin, Fecal
Regulation Number:	21 CFR 866.5180
Product Code:	NXO
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- BÜHLMANN fCAL® turbo, K191718, BÜHLMANN Laboratories AG

IV. Device Description

The BÜHLMANN fCAL® turbo, a particle-enhanced turbidimetric immunoassay (PETIA), is performed using patient stool extracts collected without preservatives. Calprotectin within the sample extract mediates immunoparticle agglutination; sample turbidity is proportional to calprotectin concentration. The detected light absorbance allows quantification of calprotectin concentration via interpolation of an established calibration curve. The assay is validated for use on clinical chemistry analyzers such as the Roche cobas® c501/c502 platforms.

The BÜHLMANN fCAL® turbo Reagent Kit is to be used in conjunction with the BÜHLMANN fCAL® turbo Calibrator Kit and BÜHLMANN fCAL® turbo Control Kit, which are available separately.

Sample extracts may be prepared using manual weighing extraction methods or the CALEX® Cap.

The CALEX® Cap is a single use tube filled with extraction buffer. The sampling pin houses a dosing tip which is used to obtain sufficient stool sample for the extraction process. The extraction method leads to stool specimen extracts which can be measured directly using the BÜHLMANN fCAL® turbo assay.

V. Indications for Use

The BÜHLMANN fCAL® turbo is an *in vitro* diagnostic assay intended for the quantitative measurement of fecal calprotectin, a neutrophilic protein that is a marker of intestinal mucosal inflammation, in human stool. The BÜHLMANN fCAL® turbo aids in the diagnosis of inflammatory bowel disease (IBD), specifically Crohn's disease (CD) and ulcerative colitis (UC) and aids in the differentiation of IBD from irritable bowel syndrome (IBS) in conjunction with other laboratory and clinical findings.

The BÜHLMANN CALEX® Cap is a single use tube intended for the preparation of human stool samples to be used with the BÜHLMANN fCAL® turbo.

VI. Comparison of Technological Characteristics

The subject device is identical to the predicate device with respect to indications for use and technological characteristics. There have been no changes to the assay components or the design of the CALEX® Cap since prior clearance.

The purpose of this submission is to extend the stability of the CALEX® Cap extracts. This change does not raise different questions of safety or effectiveness and is addressed by the information provided within the submission.

VII. Performance Data

Data from analytical and clinical studies from the applicant's own predicate device is leveraged in support of substantial equivalence.

Based on the results of risk assessment, an extract stability study was conducted in accordance with CLSI EP25 to support the shelf-life extension of the CALEX® Cap extracts.

VIII. Conclusion

The information provided above supports that the BÜHLMANN fCAL® turbo and CALEX® Cap are as safe and effective as the predicate device. The stability study supports the claimed extension to CALEX® Cap extract shelf-life. Therefore, it is concluded that the BÜHLMANN fCAL® turbo and CALEX® Cap are substantially equivalent to the predicate device.

----------This space intentionally left blank----------