CLEARED

K182698 LIAISON Calprotectin, LIAISON Calprotectin Control Set, LIAISON Calprotectin Calibration Verifiers, LIAISON Q.S.E.T. Buffer, LIAISON Q.S.E.T. Device

Dec 26, 2018
90 days to decision

K182698 · Product code: **NXO** · Immunology
Source: https://www.510kdatabase.net/k182698/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calprotectin, Fecal (NXO)
Date received	Sep 27, 2018
Decision date	Dec 26, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**DiaSorin, Inc.**
Location	Ellicott City, MD, US
Contact	John C. Walter
510(k) history	71 submissions · 70 cleared · 1998-2026

CLINICAL EVIDENCE - NCT03143517

Fecal Calprotectin Collection Protocol

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	240 patients (actual)
Study sites	13 sites
Condition studied	Inflammatory Bowel Diseases; Irritable Bowel Syndrome; Ulcerative Colitis; Crohn Disease; Indeterminate Colitis; Chronic Diarrhea; Celiac Disease; Diverticulitis; Abdominal Pain; Distension; Weight Loss; Food Intolerance; Constipation
Study type	Observational
Completion date	Aug 23, 2018
Sponsor	DiaSorin Inc. (Industry)

Primary outcome

Calprotectin Stool Collection

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03143517