July 26, 2022

DiaSorin Inc.
Christa Blaisdell
Senior Regulatory Specialist
1951 Northwestern Ave
Stillwater, Minnesota 55082

Re: K213858
Trade/Device Name: LIAISON Calprotectin, LIAISON Q.S.E.T. Device Plus
Regulation Number: 21 CFR 866.5180
Regulation Name: Fecal Calprotectin Immunological Test System
Regulatory Class: Class II
Product Code: NXO
Dated: December 9, 2021
Received: December 10, 2021

Dear Christa Blaisdell:

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, 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)*
K213858

Device Name
LIAISON® Calprotectin
LIAISON® Q.S.E.T. Device Plus

Indications for Use *(Describe)*
The DiaSorin LIAISON® Calprotectin assay is an in vitro diagnostic chemiluminescent immunoassay (CLIA) intended for the quantitative measurement, in human stool, of fecal calprotectin, a neutrophilic protein that is a marker of mucosal inflammation. The LIAISON® Calprotectin assay can be used as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome (IBS). Test results are to be used in conjunction with information obtained from the patients' clinical evaluation and other diagnostic procedures.

The test has to be performed on the LIAISON® Analyzer Family.

The DiaSorin LIAISON® Q.S.E.T. Device Plus (Quantitative Stool Extraction and Test) is intended for use in the preparation of human stool specimens for testing in the LIAISON® Calprotectin assay.

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.

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"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

SUBMITTED BY: Christa Blaisdell
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DATE PREPARED: July 25, 2022

NAME OF DEVICE:

Trade Name: LIAISON® Calprotectin
LIAISON® Q.S.E.T. Device Plus

Common Names/Descriptions: Calprotectin assay

Classification Names: Fecal calprotectin immunological test system: Class II, 21 CFR: 866.5180; Immunology (82)

Product Code: NXO

PREDICATE DEVICES : LIAISON® Calprotectin, LIAISON® Q.S.E.T. Device (K182698)

DEVICE DESCRIPTION:

INTENDED USE:
The DiaSorin LIAISON® Calprotectin assay is an *in vitro* diagnostic chemiluminescent immunoassay (CLIA) intended for the quantitative measurement, in human stool, of fecal calprotectin, a neutrophilic protein that is a marker of mucosal inflammation. The LIAISON® Calprotectin assay can be used as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome (IBS). Test results are to be used in conjunction with information obtained from the patients' clinical evaluation and other diagnostic procedures.

The test has to be performed on the LIAISON® Analyzer family.

The DiaSorin LIAISON® Q.S.E.T. Device Plus (Quantitative Stool Extraction and Test) is intended for use in the preparation of human stool specimens for testing in the LIAISON® Calprotectin assay.

INDICATIONS FOR USE
Same as intended use.

KIT DESCRIPTION:

The LIAISON® Calprotectin assay is a sandwich assay that uses 2 monoclonal antibodies for capture and detection of calprotectin. The LIAISON® Calprotectin assay must be run on the LIAISON® Analyzer family, a fully automated system with continuous loading.

Calprotectin is first extracted from human stool samples with LIAISON® Q.S.E.T. Buffer using either the weigh method, the LIAISON® Q.S.E.T. Device or the LIAISON® Q.S.E.T. Device Plus. The assay incubates extracted sample, calibrator, control, or calibration verifiers with assay buffer and paramagnetic particles coated with a monoclonal antibody that specifically recognizes the calprotectin heterocomplex. Following incubation, a wash cycle is performed to remove any unbound material. An isoluminol conjugated monoclonal antibody that recognizes calprotectin is then added to the reaction and incubated. The unbound conjugate is removed with a second wash step. Starter reagents are then added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of calprotectin present in the calibrators, controls or samples.
All assay steps and incubations are performed by the LIAISON® XL Analyzer. The analyzer software automatically calculates the concentration of calprotectin in the sample. This concentration is expressed in µg/g.

COMPARISON WITH PREDICATE

The LIAISON® Calprotectin assay is the same as cleared for the market by K182968, with additional specimen stability claims included within the Instructions for Use.

The Q.S.E.T. Device Plus differs from its predicate Q.S.E.T. Device in that it is provided ready to use, and comes prefilled with the same extract buffer as required for use with the Q.S.E.T. Device, eliminating the need for the user to prepare the buffer and add it to the device themselves. In addition, minor changes to the shape and design of the tube were made.

A comparison of the similarities and differences between the devices are provided in the following tables.

Table 1: Comparison of the LIAISON® Calprotectin assay to the predicate device

Characteristic	**Predicate Device LIAISON® Calprotectin (K182698 cleared 12/26/2018)**	**Updated Device LIAISON® Calprotectin**
Intended use/Indications for Use	The DiaSorin LIAISON® Calprotectin assay is an in vitro diagnostic chemiluminescent immunoassay (CLIA) intended for the quantitative measurement, in human stool, of fecal calprotectin, a neutrophilic protein that is a marker of mucosal inflammation. The LIAISON® Calprotectin assay can be used as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome (IBS). Test results are to be used in conjunction with information obtained from the patients' clinical evaluation and other diagnostic procedures. The test has to be performed on the LIAISON® XL Analyzer. The DiaSorin LIAISON® Q.S.E.T. Device (Quantitative Stool Extraction and Test) is intended for use in the preparation of human stool specimens for testing in the LIAISON® Calprotectin assay.	The DiaSorin LIAISON® Calprotectin assay is an in vitro diagnostic chemiluminescent immunoassay (CLIA) intended for the quantitative measurement, in human stool, of fecal calprotectin, a neutrophilic protein that is a marker of mucosal inflammation. The LIAISON® Calprotectin assay can be used as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome (IBS). Test results are to be used in conjunction with information obtained from the patients' clinical evaluation and other diagnostic procedures. The test has to be performed on the LIAISON® Analyzer Family. The DiaSorin LIAISON® Q.S.E.T. Device Plus (Quantitative Stool Extraction and Test) is intended for use in the preparation of human stool specimens for testing in the LIAISON® Calprotectin assay.
Principles of operation	Sandwich assay that uses 2 monoclonal antibodies for capture and detection of calprotectin	Same
Materials provided	Magnetic particles (2.4 mL) Conjugate (25.0 mL) Assay Buffer (27.0 mL) Specimen Diluent (13.0 mL) Number of tests: 100 Calibrator 1 (2 x 1.0 mL) Calibrator 2 (2 x 1.0 mL)	Same
Optional Laboratory Supplies	LIAISON® Q.S.E.T. Device (REF 319050)	LIAISON® Q.S.E.T. Device (REF 319050) LIAISON® Q.S.E.T. Device Plus (REF 319060)
Reagent stability (unopened, 2-8°C)	Up to the expiration date	Same
Reagent stability (opened, 2-8°C)	Upright or on board the Analyzer for 56 days	Same

Characteristic	Predicate Device LIAISON® Calprotectin (K182698 cleared 12/26/2018)	Updated Device LIAISON® Calprotectin
Calibrator stability (Room temperature)	6 hours	Same
Calibrator stability (2-8°C)	28 days	Same
Specimen storage stability (Room temperature)	No value provided	Stable up to 6 hours
Specimen storage stability (2-8°C)	72 hours	Same
Specimen storage stability (-20°C)	Store frozen at -20°C or below.	Stable up to 16 weeks frozen at -20°C
Specimen extract storage stability (Room temperature, 18-25°C)	4 hours	Same
Specimen extract storage stability (2-8°C)	6 hours	Same
Specimen extract storage stability (-20°C)	No value provided	Stable 7 days
Specimen extract storage stability (Freeze/thaw cycle)	No value provided	Stable through 1 freeze/thaw cycle
Partial Specimen extract storage stability (Room temperature)	NA	Stable 8 hours
Partial Specimen extract storage stability (2-8°C)	NA	Stable 7 days

Table 2: Comparison of the LIAISON® Q.S.E.T. Device Plus to the predicate device

Characteristic	**Predicate Device LIAISON® Q.S.E.T. Device (K182698 cleared 12/26/2018)**	**Updated Device LIAISON® Q.S.E.T. Device Plus**
Intended use	The DiaSorin LIAISON® Q.S.E.T. Device Plus (Quantitative Stool Extraction and Test) is intended for use in the preparation of human stool specimens for testing in the LIAISON® Calprotectin and/or LIAISON® Elastase-1 assays.	Same
Physical attributes	Flat bottom tube with cap 2 caps: 1 for tube, 1 cap includes sampling wand and funnel Sampling wand Funnel to remove excess stool Material: polypropylene	Round bottom tube (longer and wider) 1 cap includes sample wand and funnel Wand length is longer to accommodate larger tube Same Same
Average volume of sample collected	11.8 mg	11.3 mg
Materials provided	Polypropylene mixing tube with black funnel, screw cap, and white sampling wand with blue cap.	Polypropylene mixing tube with black funnel, screw cap, and white sampling wand with blue cap. The tube contains 6.0 mL of Q.S.E.T. Buffer, a buffered solution containing BSA, surfactant, 0.1% ProClin®300 and 0.05% gentamicin sulfate.
Number of Tests	100 devices. Each device is for 1 time use Provided separately, not included with kit	Same
Method	LIAISON® Q.S.E.T. Buffer is provided separately. User must prepare buffer and add to device.	Device is pre-filled with LIAISON® Q.S.E.T. Buffer. Ready to Use.
Storage	Room temperature	2-8°C

PERFORMANCE DATA:

PRECISION/REPRODUCIBILITY:

LIAISON® Q.S.E.T. DEVICE PLUS EXTRACTION REPRODUCIBILITY

LIAISON® Q.S.E.T. Device Plus extraction reproducibility was tested using five (5) stool samples spanning the analytical measuring range of the assay. Samples were extracted using the LIAISON® Q.S.E.T. Device Plus and tested once (1) per day using six (6) replicates over five (5) days by three (3) operators, for a total of 90 measurements per sample. Each LIAISON® Q.S.E.T. Device Plus extraction was performed daily by each operator independently. CLSI document EP15-A3 was consulted in the preparation of the testing protocol.

Table 6: Precision/Reproducibility

Sample ID	N	mean	Repeatability		Between-Day		Within-Operator		Between-Operator		Total	
		µg/g	SD (µg/g)	%CV	SD (µg/g)	%CV	SD (µg/g)	%CV	SD (µg/g)	%CV	SD (µg/g)	%CV
Sample 1	90	17.2	0.42	2.5%	1.39	8.1%	1.45	8.4%	1.26	7.3%	1.81	10.5%
Sample 2	90	37.9	0.88	2.3%	5.63	14.9%	5.69	15.0%	4.29	11.3%	6.67	17.6%
Sample 3	90	120	2.43	2.0%	12.1	10.1%	12.3	10.3%	6.29	5.2%	12.7	10.6%
Sample 4	90	264	7.27	2.8%	29.3	11.1%	30.0	11.4%	24.5	9.3%	36.5	13.8%
Sample 5	90	1018	36.3	3.6%	119	11.7%	124	12.1%	69.4	6.8%	131	12.9%

Reproducibility

LIAISON® Q.S.E.T. Device Plus sampling reproducibility was tested using 5 human stool specimens ranging from 2 – 7 on the Bristol Stool Form Scale (BSFS) which were sampled by 3 operators with 5 replicates per specimen per operator on 3 lots of devices for a total of 225 sampling events. The weight of each sample collected by the Q.S.E.T. Device Plus was determined by comparison against the empty device. Repeatability was assessed across all 5 specimens, replicates, operators, and lots.

Table 7: LIAISON® Q.S.E.T. Device Plus Stool Weight Precision Results

Precision of Q.S.E.T. Plus sample weight						
Sample	BSFS	Sample Weight (mg Mean ±SD)	Repeatability	Between-Operator	Between-Lot	Within-Lab
			(% CV)			
1	2	10.23 ±1.05	10.29	0.00	0.00	10.29
2	4	11.02 ±0.87	7.91	0.00	0.00	7.91
3	6	12.00 ±0.71	5.56	0.00	2.04	5.93
4	7	11.39 ±0.91	7.37	3.14	0.00	8.01
5	5	11.79 ±0.73	6.21	0.00	0.00	6.21

Table 8 : Sample collection performance of LIAISON® Q.S.E.T. Device Plus

Mean Sample Weight	11.3 mg
Median Sample Weight	11.4 mg
Range	8.5-13.5 mg
95% CI	11.2-11.4 mg
SD	1.06
%CV	9.38%

REAGENT STABILITY

Table 9: Reagent Stability

LIAISON® Q.S.E.T. Device Plus	Stability
2 - 8°C	12 months

SPECIMEN STABILITY

Studies were performed to determine the stability of sample at different storage conditions. The results are provided in the tables below.

Table 10: Specimen Stability

Stool Specimen	
Storage Condition	**Stability**
Refrigerated at 2- 8°C	72 hours
Room temperature (18 - 25°C)	6 hours
Frozen at -20°C	16 weeks
Freeze/Thaw cycles	3 cycles

Sample Extract – LIAISON® Q.S.E.T. Device/Plus Methods	
Storage Condition	**Stability**
Room temperature (18 - 25°C)	4 hours
Refrigerated at 2- 8°C	6 hours
Frozen at -20°C	7 days
Freeze/Thaw cycles	1 cycle
Refrigerated at 2- 8°C (with centrifugation)	7 days

Partial Sample Extract – LIAISON® Q.S.E.T. Device Plus Methods	
Storage Condition	**Stability**
Room temperature (18 - 25°C)	8 hours
Refrigerated at 2- 8°C	7 days

CONCLUSION:

The material submitted in this premarket notification is complete and supports a substantial equivalence decision. The labeling is sufficient and it satisfies the requirements of 21CFR 809.10.