510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K254295

B Applicant

Ortho Clinical Diagnostics Inc. (Quidel Ortho)

C Proprietary and Established Names

Sofia Lyme FIA
Sofia 2 Campylobacter FIA

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LSR	Class II	21 CFR 866.3830 - *Treponema pallidum* treponemal test reagents	MI - Microbiology
KHO	Class I, exempt	21 CFR 862.2560 - Fluorometer, For Clinical Use	CH - Clinical Chemistry
LQP	Class I, reserved	21 CFR 866.3110 - *Campylobacter fetus* serological reagents	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Sofia Lyme FIA and Sofia 2 Campylobacter FIA assays as performed on the Sofia 2 analyzer using an updated software version (v.2.0.14).

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

B Measurand:

Sofia Lyme FIA:
Anti-*Borrelia burgdorferi* (IgM and/or IgG) antibodies

Sofia 2 Campylobacter FIA:
Campylobacter jejuni, *Campylobacter coli*, *Campylobacter lari*, and *Campylobacter upsaliensis* antigens

C Type of Test:

Sofia Lyme FIA:
Lateral flow fluorescent immunoassay (FIA)

Sofia 2 Campylobacter FIA:
Lateral flow fluorescent immunoassay (FIA)

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:

Sofia Lyme FIA:
The Sofia Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from serum and plasma specimens from patients suspected of *B. burgdorferi* infection. This qualitative test is intended for use as an aid in the diagnosis of Lyme disease. A negative result does not preclude infection with *B. burgdorferi*. All positive results for IgM and/or IgG should be further tested by a corresponding second-tier western blot assay. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures. The Sofia Lyme FIA may be used with Sofia or Sofia 2.

Sofia 2 Campylobacter FIA:
Sofia 2 Campylobacter FIA employs immunofluorescence for the rapid qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. Sofia 2 Campylobacter FIA is designed to detect *C. jejuni*, *C. coli*, *C. lari* and *C. upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.

C Special Conditions for Use Statement(s):

For Prescription Use Only

D Special Instrument Requirements:

Sofia 2 v2.0.14

IV Device/System Characteristics:

A Device Description:

Sofia Lyme FIA:
The Sofia Lyme FIA is an immunofluorescence-based, lateral flow assay for detection of IgM and/or IgG antibodies to *Borrelia burgdorferi* in patient specimens. Reagents for the assay are ready-to-use and provided in the kit.
The assay uses a bidirectional test strip format to detect both IgM and IgG antibodies to *B. burgdorferi*. One side of the test strip detects IgM antibodies to *B. burgdorferi* and the other side of the test strip detects IgG antibodies to *B. burgdorferi*.
To perform the test, a patient serum or plasma specimen is obtained and added to a pre-filled vial containing the lyme running buffer. The diluted sample is then pipetted into the round sample port in the center of the Test Cassette. The Test Cassette is loaded into Sofia 2 in either the READ NOW Mode or WALK AWAY Mode.
In READ NOW Mode, the user allows the cassette to develop on the countertop for 10 minutes. In WALK AWAY Mode, the user immediately after adding the specimen to the cassette, the cassette is inserted into Sofia 2. Sofia 2 will analyze the test strip at 3, 5, 8, and 10 minutes until both IgM and IgG positive results are received. This feature allows for earlier read times.
Each Sofia Lyme FIA kit will contain one Positive and one Negative Control—each provided in separate dropper bottles. The Positive QC control is formulated with patient Lyme IgM and IgG positive plasma diluted into 1X PBS, and 0.3% Microcide is added to the solution as an antimicrobial. The Negative QC control is formulated with patient negative serum diluted into 1X PBS and 0.3% Microcide is added to the solution as an antimicrobial. External Controls will be tested by adding 2 drops to the test cassette.

Sofia 2 Campylobacter FIA:
The Sofia 2 Campylobacter FIA is an immunofluorescence-based, lateral flow assay that uses an antibody sandwich design to detect *Campylobacter*-specific antigens in stool specimens from individuals with signs and symptoms of gastroenteritis.
The patient stool sample is placed in the Specimen Tube, containing Specimen Diluent, to make the antigenic components more accessible to the test antibodies. An aliquot of the diluted sample is dispensed through a filter into the Test Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If *Campylobacter jejuni, Campylobacter coli, Campylobacter lari,* or *Campylobacter upsaliensis* specific antigens are present, they will be bound by polyclonal antibodies coupled to fluorescent microparticles that migrate through the test strip. The fluorescent microparticles containing bound antigens will be captured by monoclonal antibodies at a defined location on the test strip where they are detected by Sofia 2. If *Campylobacter jejuni, Campylobacter coli, Campylobacter lari,* or *Campylobacter upsaliensis* specific antigens are not present, the fluorescent microparticles will not be trapped by the capture antibodies nor detected by Sofia 2.
The Test Cassette is placed inside of Sofia 2 for automatically timed development ("Walk Away" mode), or pre-incubated on the bench top prior to loading into Sofia 2 ("Read Now" mode),

where Sofia 2 will scan, measure, and interpret the immunofluorescent signal using method-specific algorithms. Note that a supervisor can place Sofia 2 into Locked Walk Away mode, which only allows testing to be performed in Walk Away mode. Once testing is complete, Sofia 2 will display the test results (Positive, Negative, or Invalid) on the screen.
The fluorescence signal obtained with this assay is invisible to the unaided eye. The test results can only be obtained with the proper use of Sofia 2.

B Principle of Operation:

Sofia 2 family assays employ immunofluorescence-based lateral flow technology to perform qualitative detection of analytes in human clinical samples.

C Instrument Description Information:

1. Instrument Name:

   Sofia 2

2. Specimen Identification:

   The Sofia 2 analyzer supports specimen identification through two methods: Barcode entry and manual entry.

3. Specimen Sampling and Handling:

   The Sofia 2 analyzer supports multiple specimen types depending on the assay.
   Specimen collection is performed using the sterile swab or collection device provided or recommended in the test kit following the procedures specified in the assay-specific labeling.

4. Calibration:

   The Sofia 2 analyzer uses an automated calibration system to ensure stable optical performance and minimize signal drift. A Calibration Check must be performed at least every 30 days, or as otherwise specified in the applicable assay labeling.

5. Quality Control:

   The Sofia 2 analyzer uses Positive and Negative External Controls provided in each assay kit. External QC demonstrates that assay reagents, test cassettes, and procedures are functioning properly.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Sofia Lyme FIA

B Predicate 510(k) Number(s):

K173691

C Comparison with Predicate(s):

Device & Predicate Device(s):	PROPOSED DEVICE: K254295		PREDICATE DEVICE: K173691
Device Trade Name	Sofia Lyme FIA	Sofia 2 Campylobacter FIA	Sofia Lyme FIA
General Device Characteristic Similarities			
Intended Use/ Indications For Use	The Sofia Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from serum and plasma specimens from patients suspected of *B. burgdorferi* infection. This qualitative test is intended for use as an aid in the diagnosis of Lyme disease. A negative result does not preclude infection with *B. burgdorferi*. All positive results for IgM and/or IgG should be further tested by a corresponding second-tier western blot assay. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures. The Sofia Lyme FIA may be used with Sofia or Sofia 2.	Sofia 2 *Campylobacter* FIA employs immunofluorescence for the rapid qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. Sofia 2 *Campylobacter* FIA is designed to detect *C. jejuni*, *C. coli*, *C. lari* and *C. upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.	The Sofia Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from serum and plasma specimens from patients suspected of *B. burgdorferi* infection. This qualitative test is intended for use as an aid in the diagnosis of Lyme disease. A negative result does not preclude infection with *B. burgdorferi*. All positive results for IgM and/or IgG should be further tested by a corresponding second-tier western blot assay. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures. The Sofia Lyme FIA may be used with Sofia or Sofia 2.
Development Modes	Walk-Away and Read Now modes		Same
Development Time	10 minutes		Same
User Interface	4-inch color LCD touchscreen display		Same
User Types	Operator user, Supervisor, Service level		Same
Barcode Scanner (Cassette)	Integrated barcode scanner		Same
Assay/Instrument Interface	Drawer (manual)		Same
General Device Characteristic Differences			
Software Version	v2.0.14		v1.3.0

Software	The software has been reengineered to enhance usability and to modernize the device drivers, without requiring any hardware modifications.	The firmware provides a Graphical User Inter-face and manages the workflow, algorithms, hardware integration (camera, sensors, screen, touch, power), and all interoperability functions.
Programming Language	The firmware code is rewritten and reengineered from the same requirements in C++ (object-oriented programming paradigm).	Python (object-oriented programming paradigm)
Assay Framework	Existing assays were refactored to have algorithms, graphical user interface screens, and AMF components migrated into an assay-specific plugin that can be deployed independently of the firmware. Assay-related workflows (e.g., operator workflows and assay calculations) will no longer reside within the firmware. This architecture provides greater flexibility for allowing algorithms and user interface screens to be tailored to each individual assay.	Algorithms and screens reside in the firmware and are configured with an Assay Method File (AMF). Assay related workflows (such as operator workflows and assay calculations) reside inside of the firmware.
Assay Data Files	Assay plugin format	Assay Method File (AMF)
Operating System	Linux operating system Kernel version 5.4	Linux operating system Kernel version 4.1
Security - Data Encryption	Encryption was added for database and clinical data	Database and clinical data not encrypted
Security - User Authentication	Enhanced support for unique and complex user identification and password	Combination user identification and password available
Security - Export Files	Encryption of export setting files to USB i.e., instrument settings	Export setting files to USB were not encrypted

VI Standards/Guidance Documents Referenced:

- Content of Premarket Submissions for Device Software Functions (June 14, 2023)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (February 2026)
- Bundling Multiple Devices or Multiple Indications in a Single Submission (June 22, 2007)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The precision and reproducibility studies of the Sofia Lyme FIA were previously assessed in K173691. Refer to K173691 Decision Summary for additional details.

The precision and reproducibility studies of the Sofia 2 Campylobacter FIA were previously assessed in K211342. Refer to K211342 Decision Summary for additional details.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   The analytical specificity/interference studies of the Sofia Lyme FIA were previously assessed in K173691. Refer to K173691 Decision Summary for additional details.

   The analytical specificity/interference studies of the Sofia 2 Campylobacter FIA were previously assessed in K211342. Refer to K211342 Decision Summary for additional details.

4. Detection Limit and Assay Reportable Range:

   For the purposes of the analytical and comparison studies, previous software versions of the Sofia 2 analyzer (v1.3.0 for the Sofia Lyme FIA assay and v1.9.0 for the Sofia 2 Campylobacter FIA assay) are collectively referred to as "software version 1," and the updated software version is referred to as "software version 2."

   Sofia Lyme FIA:
   To assess the equivalency of the two software versions of the Sofia 2 analyzer, the performance of the Sofia Lyme FIA was evaluated with different dilutions of recombinant IgG and IgM antibodies to *B. burgdorferi* in negative plasma matrix. The plasma matrix consisted of individual human plasma samples collected from donors confirmed negative using the Sofia Lyme FIA. Initially, five (5) replicates were tested for each of the serial dilutions on one lot of Sofia Lyme FIA. Additional confirmatory testing was performed using 20 replicates with concentrations near the assay cut-off. Testing was performed on ten Sofia 2 analyzers (five per software version).

   Results demonstrated equivalent performance of Sofia Lyme FIA for IgG and IgM analytes using the Sofia 2 analyzer with both software versions. (**Table 1**).

Table 1. Performance of the Sofia Lyme FIA – Summary Results

IgG								
			Sofia 2 Software Version 1			Sofia 2 Software Version 2		
Test Phase	Conc. (ng/µL)	n	Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	10	0	10	0 (0)	0	10	0 (0)
Initial	6.6E+00	5	0	0	5 (100)	0	0	5 (100)
	1.32E+00	5	0	5	0 (0)	0	5	0 (0)
Confirmation	6.6E+00	20	0	0	20 (100)	0	0	20 (100)
	3.3E+00	20	0	0	20 (100)	0	1	19 (95.0)
	1.65E+00	20	0	16	4 (20.0)	0	14	6 (30.0)
IgM								
			Sofia 2 Software Version 1			Sofia 2 Software Version 2		
Test Phase	Conc. (ng/µL)	n	Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	10	0	10	0 (0)	0	10	0 (0)
Initial	9.6E+00	5	0	0	5 (100)	0	0	5 (100)
	1.92E+00	5	0	0	5 (100)	0	0	5 (100)
	3.84E-01	5	0	4	1 (20.0)	0	4	1 (20.0)
Confirmation	1.92E+00	20	0	0	20 (100)	0	0	20 (100)
	9.60E-01	20	0	0	20 (100)	0	0	20 (100)
	4.80E-01	20	0	20	0 (0)	0	20	0 (0)

Sofia 2 Campylobacter FIA:
To assess the equivalency of the two software versions of the Sofia 2 analyzer, the performance of the Sofia 2 Campylobacter FIA was determined by evaluating different dilutions of whole organism culture preparations of *Campylobacter jejuni* and *Campylobacter lari* in negative uniform fecal matrix (NUFM) and Cary Blair transport medium. The whole organism culture preparations of *C. jejuni* and *C. lari* were diluted into negative uniform fecal matrix and Cary Blair. NUFM consisted of each individual stool sample diluted in phosphate-buffered saline (PBS). Initially, five (5) replicates were tested for each of the serial dilutions on one lot of Sofia 2 Campylobacter FIA. Additional confirmatory testing was performed using 20 replicates with concentrations near the assay cut-off. Testing was performed on ten Sofia 2 analyzers (5 per software version).

Results demonstrated equivalent performance of Sofia 2 Campylobacter FIA using the Sofia 2 analyzer with both software versions for the *Campylobacter* spp. evaluated. The results of the study are shown in **Table 2** and **Table 3**.

Table 2. Performance of the Sofia 2 Campylobacter FIA – Summary Results for *C. jejuni*

Negative Uniform Fecal Matrix (CFU/mL)								
			Sofia 2 Software Version 1			Sofia 2 Software Version 2		
Test Phase	Conc. (CFU/mL)	n	Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	2.0E+06	5	0	0	5 (100)	0	0	5 (100)
	4.0E+05	5	0	0	5 (100)	0	0	5 (100)
	8.0E+04	5	0	1	4 (80.0)	0	2	3 (60)
Confirmation	8.0E+05	20	0	0	20 (100)	0	0	20 (100)
	4.0E+05	20	0	0	20 (100)	0	0	20 (100)
	2.0E+05	20	0	20	0 (0)	0	19	1 (5.0)
Cary Blair (CFU/mL)								
			Sofia 2 Software Version 1			Sofia 2 Software Version 2		
Test Phase	Conc. (CFU/mL)	n	Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	5.0E+05	5	0	0	5 (100)	0	0	5 (100)
	1.0E+05	5	0	0	5 (100)	0	0	5 (100)
	2.0E+04	5	0	1	4 (80.0)	0	2	3 (60)
Confirmation	2.0E+05	20	0	0	20 (100)	0	0	20 (100)
	1.0E+05	20	0	0	20 (100)	0	0	20 (100)
	5.0E+04	20	0	20	0 (0)	0	19	1 (5.0)

Table 3. Performance of the Sofia 2 Campylobacter FIA – Summary Results for *C. lari*

Negative Uniform Fecal Matrix (CFU/mL)								
			Sofia 2 Software Version 1			Sofia 2 Software Version 2		
Test Phase	Conc. (ng/µL)	n	Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	4.0E+06	5	0	0	5 (100)	0	0	5 (100)
	8.0E+0.5	5	0	0	5 (100)	0	1	4 (80.0)
	1.6E+05	5	0	5	0 (0)	0	5	0 (0)
Confirmation	1.6E+07	20	0	0	20 (100)	0	0	20 (100)
	8.0E+06	20	0	0	20 (100)	0	0	20 (100)
	4.0E+06	20	0	20	0 (0)	0	20	0 (0)
Cary Blair (CFU/mL)								
			Sofia 2 Software Version 1			Sofia 2 Software Version 2		
Test Phase	Conc. (ng/µL)	n	Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	1.0E+06	5	0	0	5 (100)	0	0	5 (100)
	2.0E+05	5	0	0	5 (100)	0	0	5 (100)
	4.0E+04	5	0	4	1 (20.0)	0	4	1 (20.0)
Confirmation	4.0E+06	20	0	0	20 (100)	0	0	20 (100)
	2.0E+06	20	0	0	20 (100)	0	0	20 (100)
	1.0E+06	20	0	20	0 (0)	0	20	0 (0)

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The stability studies of the Sofia 2 Campylobacter FIA were previously assessed in K211342. Refer to K211342 Decision Summary for additional details.

6. Assay Cut-Off:

Sofia Lyme FIA:
To evaluate performance near the assay cut-off for the Sofia Lyme FIA, a panel of samples were contrived by spiking recombinant IgG and IgM antibodies to *B. burgdorferi* in negative plasma matrix. Samples were tested with the Sofia 2 analyzer with software version 1 and version 2. The panel included a negative sample, low positive sample and moderate positive sample for both recombinant IgG and IgM antibodies. Samples were tested in triplicate over five (5) days, two (2) runs per day, with at least two (2) operators, yielding 30 replicates per sample. Testing was performed on 20 analyzers (10 per software version) using one lot of Sofia Lyme FIA.

All positive and negative samples yielded 100% agreement to the expected result with the Sofia 2 analyzer software version 1 and version 2. Performance of the Sofia Lyme FIA near the assay cut-off was equivalent between Sofia 2 analyzer software version 1 and version 2 for IgG and IgM antibodies.

Sofia 2 Campylobacter FIA:
To evaluate performance near the assay cut-off for the Sofia 2 Campylobacter FIA, a panel of samples were contrived by spiking whole organism culture preparations of *C. jejuni* and *C. lari* in negative uniform fecal matrix (NUFM) and processed in Cary Blair transport medium were tested with the Sofia 2 analyzer software version 1 and version 2. The panel included a negative sample, low positive sample and moderate positive sample for both *C. jejuni* and *C. lari*. Samples were tested in triplicate over five (5) days, two (2) runs per day, with at least two (2) operators, yielding 30 replicates per sample. Testing was performed on 20 analyzers (10 per software version) using one lot of Sofia 2 Campylobacter FIA.

All positive and negative samples yielded 100% agreement to the expected result with the Sofia 2 analyzer software version 1 and version 2 for *C. jejuni* and *C. lari*. Performance of the Sofia 2 Campylobacter FIA near the assay cut-off was equivalent between Sofia 2 analyzer software version 1 and version 2 for the *Campylobacter* spp. evaluated.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Sofia Lyme FIA:
The performance of the Sofia Lyme FIA was evaluated by performing a method comparison study with the Sofia 2 analyzer with software version 1 and version 2. Contrived positive and negative samples were prepared in negative plasma matrix collected from individual donors confirmed negative using the Sofia Lyme FIA. Equivalency between serum and plasma matrices was previously established in K173691; therefore, only plasma samples were tested. Positive samples were spiked independently with recombinant IgG or IgM antibodies to *B. burgdorferi*. The test panel consisted of 30 negative samples and 50 positive samples.

Positive samples were comprised of 18 low positive samples, 17 moderate positive samples, and 15 moderate to high positive samples per analyte. Prior to testing, all samples were coded and randomized and confirmed on the Sofia 2 analyzer using software version 1. Testing was performed on 10 Sofia 2 analyzers (5 per software version) operating in Read Now mode using a single lot.

All IgG positive samples yielded 100% agreement to the expected result with the Sofia 2 analyzer and software version 2. There was one IgG positive sample prepared at 5-10x LoD that yielded an unexpected IgM-positive result with the Sofia 2 analyzer and software version 1. IgM positive samples yielded 98.0% (49/50) agreement to the expected result with the Sofia 2 analyzer and software version 2. There was one IgM positive sample prepared at 1x LoD that yielded a negative result with the Sofia 2 analyzer and software version 2. All negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for IgG and IgM antibodies. Results demonstrated equivalent performance of Sofia Lyme FIA for IgG and IgM analytes using the Sofia 2 analyzer with both software versions.

Sofia 2 Campylobacter FIA:
The performance of the Sofia 2 Campylobacter FIA was evaluated by performing a method comparison study with the Sofia 2 analyzer with software version 1 and version 2. Contrived positive and negative samples were prepared in negative uniform fecal matrix collected from individual healthy donors and processed in Cary Blair transport media. Positive samples were spiked independently with *C. jejuni* or *C. lari.* The test panel consisted of 30 negative samples and 50 positive samples. Positive samples were comprised of 18 low positive samples, 17 moderate positive samples, and 15 moderate to high positive samples per analyte. Prior to testing, all samples were coded and randomized and confirmed on the Sofia 2 analyzer using software version 1. Testing was performed on 10 Sofia 2 analyzers (5 per firmware version) operating in Read Now mode using a single lot.

All positive and negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for *C. jejuni* and *C. lari*. Results demonstrated equivalent performance of Sofia 2 Campylobacter FIA using the Sofia 2 analyzer with both software versions for the *Campylobacter* spp. evaluated.

2. Matrix Comparison:

The plasma and serum matrix equivalency studies of the Sofia Lyme FIA were previously assessed in K173691. Refer to K173691 Decision Summary for additional details.

C Clinical Studies:

1. Clinical Sensitivity:

   The clinical sensitivity studies of the Sofia Lyme FIA were previously assessed in K173691. Refer to K173691 Decision Summary for additional details.

   The stability studies of the Sofia 2 Campylobacter FIA were previously assessed in K211342. Refer to K211342 Decision Summary for additional details.

2. Clinical Specificity:

   Not applicable.

3. Clinical Cut-Off

   Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   The clinical supportive studies of the Sofia Lyme FIA were previously assessed in K173691. Refer to K173691 Decision Summary for additional details.

D Expected Values/Reference Range:

Not applicable.

E Other Supportive Instrument Performance Characteristics Data:

Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.