July 10, 2026

Ortho-Clinical Diagnostics, Inc. (QuidelOrtho)
Xiaoxi Wang
Regulatory Affairs Manager
9975 Summers Ridge Rd.
San Diego, California 92121

Re: K254295
Trade/Device Name: Sofia Lyme FIA; Sofia 2 Campylobacter FIA
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR, KHO, LQP
Dated: June 5, 2026
Received: June 8, 2026

Dear Xiaoxi Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254295

Device Name
Sofia Lyme FIA

Indications for Use *(Describe)*

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 diagno-sis 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.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254295

Device Name
Sofia 2 Campylobacter FIA

Indications for Use *(Describe)*

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.

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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510(K) SUMMARY

Submitter

Ortho-Clinical Diagnostics, Inc. (QuidelOrtho)

9975 Summers Ridge Road

San Diego, CA 92121

United States

Submission Contact

Name: Xiaoxi Wang

Title: Regulatory Affairs Manager

Email: xiaoxi.wang@quidelortho.com

Purpose of This Submission

This submission pertains to the Sofia 2 software update (V2.0.14 software) for Sofia Lyme FIA and Sofia 2 Campylobacter FIA.

Proprietary and Established Name

Sofia Lyme FIA

Sofia 2 Campylobacter FIA

Type Of Device

Qualitative

Classification

Regulation Description	Classification	Product code	Regulation Number	Panel
Treponema pallidum treponemal test reagents	Class II	LSR	866.3830	Microbiology
Campylobacter fetus serological reagents.	Class I, reserved	LQP	866.3110	Microbiology
Fluorometer for clinical use	Class I	KHO	862.2560	Clinical Chemistry

Predicate Device
Predicate Device #: K173691

Predicate Trade Name: Sofia Lyme FIA

Product Code: LSR

Device Description

The Sofia 2 is a microprocessor-controlled device about the size of a desktop telephone and weighs less than 3 pounds. It uses a fluorescent tag that is illuminated by an Ultraviolet (UV) light source to generate specific assay results.

The Sofia 2 microprocessor-controlled optics unit images the nitrocellulose test strip, thereby exposing the strip to UV light from UV LEDs with a peak emission at 365 nm. The UV light excites the europium fluorophore, which in turn emits light at a wavelength of 618 nm. This is captured by a camera positioned over the strip. A positive result for the analyte is determined by detection of fluorescent signals at the Test Line above a specific cutoff.

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

This Premarket Notification is being submitted for a modification to the Sofia 2 analyzer. The modification consists of a software update from version 1 to version 2.0.14. Key changes include:

- The software and firmware are reengineered to improve usability and modernize the device drivers, without requiring any hardware updates.
- The infrastructure programming language is changed from Python to C++, both of which are object-oriented programming paradigms.
- The existing Sofia 2 assays are refactored so that their algorithms, screens, and assay method files (AMFs) are moved into assay plugins that can be deployed independently of the firmware.
- The underlying operating system and device drivers are modernized.
- Cybersecurity OTS EOL remediation and implementation of enhanced cybersecurity controls.
- The Supervisor screen menus are revised to enhance ease of use.

There are **no changes** to the intended use, assay workflows, performance claims, test result screen content, or interpretation algorithms. The algorithms are unchanged and are directly leveraged from the previous Sofia 2 firmware version 1.

Note: No hardware changes are included in the Sofia 2 software update. The design change is limited to software modifications only. There are also no changes to cassette technology or assay intended use.

Intended Use

Sofia Lyme FIA Intended 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 Intended Use

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.

Comparison to Predicate

Sofia 2 v2.0.14 introduces the modifications and updated features. These differences do not affect the overall substantial equivalence of the proposed device to the predicate device in terms of intended use, design, safety, or effectiveness.

Device Comparison Table for Sofia Lyme FIA

Features	Predicate Device Sofia Lyme FIA (K173691) [Sofia 2 version 1.3.0]	Modified Device Sofia Lyme FIA [Sofia 2 version 2.0.14]	Modified Device Sofia 2 Campylobacter FIA [Sofia 2 version 2.0.14]
Assay Intended 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.	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.
Development Modes	Two basic assay development modes: • Walk-Away: User can walk away during the assay cassette development period • Read Now: User manually times the assay cassette development period outside of Sofia, then places cassette in Sofia to scan and provide test result.	Same	
Barcode Scanner (cassette)	Integrated barcode scanner	Same	
Assay/instrument interface	Drawer (manual)	Same	
Power Supply	100 – 240 VAC, self-switching, or with rechargeable lithium polymer battery	Same	
Dimensions	19.7 cm deep x 11.4 cm wide x 12.7 cm high	Same	
Weight	~2.5 lbs	Same	

System and Software Differences Between Sofia 2 Analyzer Version 1 and Version 2.0.14

Characteristics/ Function	Predicate Device Sofia Lyme FIA (K173691) [Sofia 2 version 1.3.0]	Modified Device Sofia Lyme FIA [Sofia 2 version 2.0.14]	Modified Device Sofia 2 Campylobacter FIA [Sofia 2 version 2.0.14]
Differences			
Software	The firmware provides a Graphical User Interface and manages the workflow, algorithms, hardware integration (camera, sensors, screen, touch, power), and all interoperability functions.	Same features and functionality. The software has been reengineered to enhance usability and to modernize the device drivers, without requiring any hardware modifications.	
Programming Language	Python (object-oriented programming paradigm)	The firmware code is rewritten and reengineered from the same requirements in C++ (object-oriented programming paradigm).	
Assay framework	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.	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.	
Operating System	Linux operating system Kernel version 4.1	Linux operating system Kernel version 5.4	
Security	Database and clinical data not encrypted	Encryption was added for database and clinical data	
	Combination user identification and password available	Enhanced support for unique and complex user identification and password	
	Export setting files to USB were not encrypted	Encryption of export setting files to USB i.e., instrument settings	

Performance Data

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate device. These studies included the following:

Various Analytical Studies

Analytical evaluations—including Limit of Detection, Near-Cutoff, and Method Comparison studies—were conducted for the Sofia 2 family assays (Sofia Lyme FIA, Sofia 2 Campylobacter FIA) using both Sofia 2 Software Version 1 and Sofia 2 Software Version 2.

All studies demonstrated equivalency between Sofia 2 Software Version 1and Sofia 2 Software Version 2 for Sofia 2 family assays (Sofia Lyme FIA, Sofia 2 Campylobacter FIA).

EMC Compatibility and Electrical Safety

Sofia 2 analyzer was evaluated by accredited laboratories for electromagnetic compatibility and electrical safety.

Shelf Life

The Sofia 2 analyzer does not have an expiration date. The software modification included in this submission does not impact the established shelf life of any Sofia 2 family assays (Sofia Lyme FIA, Sofia 2 Campylobacter FIA).

Conclusion

Sofia Lyme FIA and Sofia 2 Campylobacter FIA, when used with the Sofia 2 analyzer (firmware version 2.0.14) are **substantially equivalent** to the predicate devices: Sofia Lyme FIA and Sofia 2 Campylobacter FIA used with the Sofia 2 analyzer (firmware version 1). The modifications do not alter the intended use, contraindications, technological characteristics, operating principle, user interface ergonomics, safety features, or performance characteristics of the device. No hardware or cassette modifications were made.

In summary, Sofia Lyme FIA and Sofia 2 Campylobacter FIA, when used with the Sofia 2 analyzer (firmware version 2.0.14), remains substantially equivalent in safety and effectiveness to the predicate devices. This Summary of Safety and Effectiveness is submitted in accordance with 21 CFR 807.92.