February 28, 2018

Quidel Corporation
Jennifer Rial
Director, Regulatory Affairs
12544 High Bluff Drive, Suite 200
San Diego, California 92130

Re: K173691
Trade/Device Name: Sofia Lyme FIA, Sofia 2 analyzer, Sofia 2 Installation Pack
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: November 29, 2017
Received: December 1, 2017

Dear Jennifer Rial:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kristian M. Roth -S For:

Uwe Scherf, M.S., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173691

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 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.

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.

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5. 510(K) SUMMARY

5.1. Submitter

Quidel Corporation
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San Diego, California 92130
Telephone: 858-552-7910
Fax: 858-646-8045

5.2. Submission Contact

Jennifer S. Rial

5.3. Date Prepared

November 29, 2017

5.4. Proprietary and Established Names

Sofia Lyme FIA

5.5. Common Name

Lyme IgG and Lyme IgM test

5.6. Regulatory Information

Product Code	Classification	Regulatory Section	Panel
LSR	II	21 CFR 866.3830	Immunology and Microbiology Devices

5.7. Predicate Device

Vidas Lyme IgG and Vidas Lyme IgM

5.8. Device Description

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.

5.9. 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.

5.10. Substantial Equivalence Information:

1. Predicate Device Name: Vidas Lyme IgM and Vidas Lyme IgG

2. Predicate 510(k) Numbers: K122979 and K122986

Comparison with Predicate

Item	Proposed Device	Predicate IgM Device	Predicate IgG Device
Features	**Sofia Lyme FIA with Sofia**	**Biomerieux Vidas Lyme IgM**	**Biomerieux Vidas Lyme IgG**
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 VIDAS Lyme IgM assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burdorferi* in human serum or plasma. It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.	The VIDAS Lyme IgG assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burdorferi* in human serum or plasma. It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.
Instrument	Sofia 2 (and Sofia)	VIDAS and miniVIDAS	VIDAS and miniVIDAS

Item	Proposed Device	Predicate IgM Device	Predicate IgG Device
Features	**Sofia Lyme FIA with Sofia**	**Biomerieux Vidas Lyme IgM**	**Biomerieux Vidas Lyme IgG**
Analyte	Human IgM and IgG antibodies against *B. burgdorferi* proteins	Human IgM antibodies against *B. burgdorferi* proteins	Human IgG antibodies against *B. burgdorferi* proteins
Automated Analysis	Yes	Yes	Yes
Read Results	Read results on instrument screen or print with optional printer	Result report is printed	Result report is printed
Read Result Time	Sofia 2 - Potential for early read in Walk-Away Mode with Sofia 2. Sofia 2 will image cassette at 3, 5, 8, and 10 minutes until both IgM and IgG positive results are received. Sofia – 10 minutes	27 minutes	27 minutes
Specimen Types	Serum and plasma	Serum and plasma	Serum and plasma
Qualitative	Yes	Yes	Yes
Test Principle	Immunofluorescence Device	Immunofluorescence Device	Immunofluorescence Device
Format	Lateral-flow Bi-directional Test Cassette	Enzyme-linked fluorescent assay (ELFA)	Enzyme-linked fluorescent assay (ELFA)
Antibodies Used	Monoclonal anti-human IgG and polyclonal anti-human IgM	Anti-human IgM antibodies	Anti-human IgG antibodies
Antigens Used	Recombinant Proteins and synthetic peptides of *B. burgdorferi*	Recombinant proteins of *B. burgdorferi*	Recombinant proteins of *B. burgdorferi*
Detection Method	Polystyrene microparticles dyed with Europium chelate	Alkaline phosphatase/4-MUP	Alkaline phosphatase/4-MUP
Storage	Room Temperature (15-30°C)	2-8°C	2-8°C
Running Buffer Solution	One pre-filled vial containing PBS	Sample diluent and wash buffer	Sample diluent and wash buffer

Item	Proposed Device	Predicate IgM Device	Predicate IgG Device
Features	**Sofia Lyme FIA with Sofia**	**Biomerieux Vidas Lyme IgM**	**Biomerieux Vidas Lyme IgG**
Quality Control Features	Built-in features include: • Built-in procedural control zone scanned by the analyzer to determine whether adequate flow occurred on the IgG side of the assay. • Built-in reference control line scanned by the analyzer to determine whether adequate flow occurred on the IgM side of the assay. • Analyzer prevents used or expired cartridge from being read by the reader • Cassette must be properly inserted	• One positive and one negative control are included and must be tested after opening a new kit to monitor reagent failure.	• One positive and one negative control are included and must be tested after opening a new kit to monitor reagent failure.

5.11. Performance Data

Additional studies were performed to document the performance characteristics of Sofia Lyme FIA with the Sofia 2 analyzer. The studies included the following:

a. Various Analytical Studies
Analytical studies included Limit of Detection, Sofia and Sofia 2 Comparison, Matrix Comparison, Early Read, System Temperature (Read Now vs. Walk Away). All studies demonstrated good performance.

b. Precision
This study evaluated the within laboratory precision / repeatability of the Sofia Lyme FIA and the Sofia 2 analyzer. The total precision results for IgM and IgG were not significantly different within-run, within-day, between day and total when tested with the negative (C0), high negative (C5), low positive (C95) and moderate positive (2-3X LOD) samples.

c. Specificity Study
This study evaluated the analytical specificity of the Sofia Lyme FIA on Sofia 2 using samples obtained from asymptomatic (healthy, normal) populations in both endemic and non-endemic regions. The overall specificity of the Sofia Lyme FIA was very good.

d. Method Comparison
This study demonstrated that Sofia Lyme FIA with Sofia 2 has comparable performance to the Vidas Lyme IgG and Vidas Lyme IgM tests when testing prospectively collected specimens from subjects suspected of having Lyme disease.

e. Reproducibility
This study demonstrated intra- and inter-laboratory reproducibility with a panel of test samples at various concentrations of IgM and IgG antibodies to *B. burgdorferi*. The operators and laboratories obtained accurate results with the Sofia Lyme FIA on Sofia 2.

5.12. Conclusion

These studies demonstrated the substantial equivalence of the Sofia Lyme FIA with Sofia 2 to the Vidas Lyme IgG and Vidas Lyme IgM tests. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.