DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 20, 2017

QUIDEL CORPORATION
JENNIFER RIAL
DIRECTOR, REGULATORY AFFAIRS
12544 HIGH BLUFF DRIVE, SUITE 200
SAN DIEGO CA 92130

Re: K163713
Trade/Device Name: Sofia Lyme Fia, Sofia Lyme Control Set
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: II
Product Code: LSR
Dated: May 17, 2017
Received: May 19, 2017

Dear Ms. 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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kristian M. Roth -S

For:

Uwe Scherf, M.Sc., 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)*
K163713

Device Name
Sofia Lyme FIA
Sofia Lyme Control Set

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 Control Set is intended for use as assayed quality control materials to verify the performance of the Sofia Lyme FIA test system.

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.

5. 510(K) SUMMARY

5.1. Submitter

Quidel Corporation
12544 High Bluff Drive, Suite 200
San Diego, California 92130
Telephone: 858-552-7910
Fax: 858-646-8045

5.2. Submission Contact

Jennifer S. Rial

5.3. Date Prepared/Updated

October 18, 2017

5.4. Proprietary and Established Names

Sofia Lyme FIA
Sofia Lyme Control Set

5.5. Common Name

Lyme IgG and Lyme IgM test and assayed external controls

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, the patient specimen (30 µL serum/plasma) is added to a pre-filled Reagent Vial. 100 µL of the diluted sample is then dispensed into the round sample well located near the center of the Test Cassette. The Test Cassette is loaded into Sofia for an automatically defined development time (WALK AWAY Mode) or pre-incubated on the bench top prior to loading into Sofia (READ NOW Mode). Sofia scans the test strip, analyzes the fluorescent signal, and then displays two (2) test results: IgM (positive, negative or invalid) and IgG (positive, negative or invalid). As an option, the results are automatically printed on the integrated printer.

Each Sofia Lyme FIA kit will contain one Positive and one Negative Control—each provided in separate dropper bottles. The external controls will be provided separately as well in a Sofia Lyme Control Set. The Positive and Negative QC controls are formulated with patient Lyme IgM and IgG positive serum that are diluted into 1X PBS and 0.3% Microcide is added to the solution as an antimicrobial. The External Controls will be tested by adding 2 drops to the test cassette.

5.9. Intended 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.

Sofia Lyme Control Set: The Sofia Lyme Control Set is intended for use as assayed quality control materials to verify the performance of the Sofia Lyme FIA test system.

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	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. Sofia Lyme Control Set: The Sofia Lyme Control Set is intended for use as assayed quality control materials to verify the performance of the Sofia Lyme FIA test system.	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	VIDAS and miniVIDAS	VIDAS and miniVIDAS
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

Item	Proposed Device	Predicate IgM Device	Predicate IgG Device
Features	**Sofia Lyme FIA with Sofia**	**Biomerieux Vidas Lyme IgM**	**Biomerieux Vidas Lyme IgG**
Read Results	Read results on instrument screen or print with optional printer	Result report is printed	Result report is printed
Read Result Time	10 Minutes	27 minutes	27 minutes
Specimen Types	Human serum and plasma	Human serum and plasma	Human 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
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	• 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.

Item	Proposed Device	Predicate IgM Device	Predicate IgG Device
Features	**Sofia Lyme FIA with Sofia**	**Biomerieux Vidas Lyme IgM**	**Biomerieux Vidas Lyme IgG**
	side of the assay. • Analyzer prevents used or expired cartridge from being read by the reader • Cassette must be properly inserted		

5.11. Performance Data

Numerous studies were undertaken to document the performance characteristics of Sofia Lyme FIA and the Sofia Lyme Control Set, as well as to compare the performance between Sofia Lyme and the Vidas IgG and IgM tests. The studies included the following:

a. Various Analytical Studies
Analytical studies included Limit of Detection, cross-reactivity, interfering substances, specimen collection and handling, operating temperature, and various flex studies. All studies demonstrated good performance.

b. Precision
This study evaluated the within laboratory precision / repeatability of the Sofia Lyme FIA using serum samples. 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. CDC Reference Panel
When testing the CDC reference panel, the overall agreement for Clinical Status of IgG and IgM samples between Sofia Lyme FIA and Western Blot was good.

d. Sensitivity Study
This study evaluated the clinical sensitivity of the Sofia Lyme FIA device using well-characterized clinically or culture confirmed Lyme disease samples. The clinical sensitivity was compared to a 510(k) cleared test and the performance was comparable.

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

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

g. 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.

5.12. Conclusion

These studies demonstrated the substantial equivalence of the Sofia Lyme FIA 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.