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

Quidel Corporation
Edward C. Brehm, PhD
Regulatory Affairs Manager
12544 High Bluff Drive, Suite 200
San Diego, CA 92130

February 22, 2017

Re: K162911
Trade/Device Name: Sofia® RSV FIA
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: I
Product Code: GQG
Dated: October 14, 2016
Received: October 24, 2016

Dear Dr. Brehm:

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,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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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)*
K162911

Device Name
Sofia® RSV FIA

Indications for Use *(Describe)*

The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared RSV molecular assay.

The Sofia RSV FIA may be used with the 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

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Telephone: 858-552-1100, X-21015
Fax: 858-646-8045

5.2. Submission Contact

Edward C. Brehm, Ph.D.

5.3. Date Prepared

February 21, 2017

5.4. Proprietary and Established Names

Sofia® RSV FIA performed on Sofia 2

5.5. Common Name

Same as above

5.6. Regulatory Information

Product Code	Classification	Regulatory Section	Panel
GQG	I	21 CFR 866.3480	Microbiology
KHO	I	21 CFR 862.2560	Clinical Chemistry per regulation; Microbiology because it is used with the Sofia RSV FIA

5.7. Predicate Device

Sofia RSV FIA performed on Sofia

5.8. Device Description

The Sofia RSV FIA test employs immunofluorescence technology that is used with Sofia for the rapid detection of RSV antigens. The Sofia RSV FIA test involves the disruption of RSV viral antigens. The patient specimen is placed in the Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After disruption, the specimen is dispensed into the Cassette sample well. From the sample well, the specimen

migrates through a test strip containing various unique chemical environments. If RSV viral antigens are present, they will be trapped in a specific location.

> **Note:** Depending upon the user's choice, the cassette is either placed inside of Sofia or Sofia 2 for automatically timed development (Walk Away Mode) or placed on the counter or bench top for a manually timed development and then placed into Sofia or Sofia 2 to be scanned (Read Now Mode).

Sofia or Sofia 2 will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Test results will be displayed (Positive, Negative, or Invalid) on the screen. The results can also be automatically printed on an integrated printer if this option is selected.

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

5.9. Intended Use

The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared RSV molecular assay.

The Sofia RSV FIA may be used with Sofia or Sofia 2.

5.10. Substantial Equivalence Information:

1. Predicate Device Name: Sofia RSV FIA performed on Sofia
2. Predicate 510(k) Numbers: K130398
3. Comparison with Predicate:

Similarities and Differences		
Item	**Sofia RSV FIA on Sofia**	**Sofia RSV FIA on Sofia 2**
510(k) Number	**K130398**	**K162911**
Intended Use	The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared RSV molecular assay.	The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared RSV molecular assay. The Sofia RSV FIA may be used with Sofia or Sofia 2.
Calibration Check	Calibration Check required every 30 days or less, as set by the supervisor. A special Calibration Cassette is provided with the Installation Pack.	Same and uses the same Calibration Cassette
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 image and provide test result.	Same
Development Time	15 minutes for Sofia RSV FIA	Potential for early read in Walk-Away Mode. Sofia 2 will image cassette at 3, 5, 8, 10, and 15 minutes until a positive result is received.
System Components		
User interface	3.5 inch diagonal color LCD display and numeric keypad with function specific buttons	4 inch color LCD touchscreen display

Similarities and Differences		
Item	**Sofia RSV FIA on Sofia**	**Sofia RSV FIA on Sofia 2**
510(k) Number	**K130398**	**K162911**
User Types	Has 2 distinct security levels; user and supervisor plus a Quidel only service level.	Same
Barcode scanner(sample)	External hand held barcode scanner	Integrated barcode scanner but same functionality
Barcode scanner(cassette)	Integrated barcode scanner	Same using custom integrated 0.3 MP camera
Assay / instrument interface	Drawer (electro-mechanical)	Same (manual)
Determine test type	Instrument scans barcode on cassette	Same
Power Supply	100 – 240 VAC, self-switching, or with 4 AA batteries	100 – 240 VAC, self-switching, or with rechargeable lithium polymer battery
Printer	Integrated printer	External printer connected via USB port (DYMO LabelWriter 450 Printer supported), optional network printer.
Dimensions	24 cm deep x 16 cm wide x 10 cm high	19.7 cm deep x 11.4 cm wide x 12.7 cm high
Weight	3 lbs	~2.5 lbs

5.11. Performance Data

Numerous studies were undertaken to document the performance characteristics of Sofia 2 and the Sofia RSV assay, as well as to compare the performance between Sofia and Sofia 2. The studies included the following:

a. Limit of Detection (LoD)
This study confirmed that the LoD generated for the Sofia RSV FIA on Sofia 2 is equivalent to the LoD generated on Sofia.

b. Precision
This study confirmed that Sofia and Sofia 2 generated equivalent qualitative results when used by multiple operators to test negative and positive concentrations that are close to the positivity threshold, on multiple device lots, operated over multiple days, and two calibration cycles.

c. Assay development time
This study confirmed that when running Sofia 2 in Read Now mode, a development time of eight (8) to thirty (30) minutes is acceptable.

d. Early Read
This study confirmed that when running Sofia 2 in Walk Away mode, positive samples (depending on the viral load) can be interpreted as positive as early as 3 minutes.

e. Method Comparison

This study demonstrated that Sofia and Sofia 2 have comparable performance when using a panel of clinical samples.

f. Reproducibility
This study demonstrated intra- and inter-operator reproducibility and intra- and inter-laboratory reproducibility with a panel of test samples at various RSV concentrations. This study also demonstrated comparable performance between Sofia and Sofia 2.

5.12. Conclusion

These studies demonstrated equivalent performance of the Sofia RSV FIA on the Sofia and Sofia 2 analyzer.