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

April 14, 2017

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

Re: K162438
Trade/Device Name: Sofia® Influenza A+B FIA on Sofia 2
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test systems
Regulatory Class: II
Product Code: PSZ
Dated: March 13, 2017
Received: March 14, 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,

Steven R. Gitterman -S for

Uwe Scherf
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)*
K162438

Device Name
Sofia® Influenza A+B FIA on Sofia 2

Indications for Use *(Describe)*
The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. This test is intended for professional and laboratory use.

The Sofia Influenza A+B FIA may be used with Sofia or Sofia 2.

Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

August 26, 2016

5.4. Proprietary and Established Names

Sofia® Influenza A+B FIA on Sofia 2

5.5. Common Name

Same as above

5.6. Regulatory Information

Product Code / Name	Class	Regulatory Section	Panel
PSZ – Devices detecting influenza a, b, and c virus antigens KHO - Fluorometer for clinical use	II	21 CFR 866.3328	Microbiology

5.7. Predicate Device

Sofia® Influenza A+B FIA on Sofia (K153012, K131606, and K112177)

5.8. Device Description

The Sofia Influenza A+B FIA employs immunofluorescence technology that is used with Sofia and Sofia 2 to detect influenza virus nucleoproteins. This test allows for the differential detection of influenza A and influenza B antigens.

The patient sample is placed in the Reagent Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the Test Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If influenza viral antigen is present, they will be trapped in a specific location.

Note: Depending upon the user's choice, the Test 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 and Sofia 2 will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. Sofia and Sofia 2 will display the test results (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 Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. This test is intended for professional and laboratory use.

The Sofia Influenza A+B FIA may be used with Sofia or Sofia 2.

Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.

5.10 Substantial Equivalence Information:

1. Predicate Device Name: Sofia Influenza A+B FIA on Sofia
2. Predicate 510(k) Numbers: K153012, K131606, and K112177
3. Comparison with Predicate:

Similarities and Differences		
Item	**Sofia Influenza A+B FIA on Sofia**	**Sofia 2 Influenza A+B FIA on Sofia and Sofia 2**
Intended Use	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash in fresh or transport media specimens from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. This test is intended for professional and laboratory use. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. This test is intended for professional and laboratory use. The Sofia Influenza A+B FIA may be used with Sofia or Sofia 2. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture samples.

Similarities and Differences		
Item	**Sofia Influenza A+B FIA on Sofia**	**Sofia 2 Influenza A+B FIA on Sofia and 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 Influenza A+B 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
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 Influenza A+B 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 Influenza A+B 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, and operated over multiple days.

c. Assay development time
This study confirmed that when running Sofia 2 in Read Now mode, a development time of fifteen (15) 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 influenza concentrations. This study also demonstrated comparable performance between Sofia and Sofia 2.

5.12. Conclusion

These studies demonstrated equivalent performance of the Sofia Influenza A+B FIA on the Sofia and Sofia 2 analyzers.