December 21, 2017

Quidel Corporation
Edward Brehm
Regulatory Affairs Manager
12544 High Bluff Drive, Suite 200
San Diego, California 92130

Re: K171976
Trade/Device Name: Sofia Strep A+ FIA, Sofia 2 Analyzer
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus spp.* serological reagents
Regulatory Class: Class I
Product Code: GTY, KHO
Dated: June 29, 2017
Received: June 30, 2017

Dear Edward 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 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,

Steven R. Gitterman -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171976

Device Name
Sofia Strep A+ FIA for use on Sofia 2

Indications for Use *(Describe)*
The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. All negative test results should be confirmed by either bacterial culture or an FDA-cleared molecular assay because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection.

The Sofia Strep A+ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

5.1. Submitter

Quidel Corporation
12544 High Bluff Drive, Suite 200
San Diego, California 92130
Telephone: 858-552-1100, X-21015
Fax: 858-646-8045

5.2. Submission Contact

Edward C. Brehm, Ph.D.

5.3. Date Prepared

June 29, 2017

5.4. Proprietary and Established Names

Sofia® Strep A+ FIA performed on Sofia 2

5.5. Common Name

Same as above

5.6. Regulatory Information

Product Code	Classification	Regulatory Section	Panel
GTY	I	21 CFR 866.3740	Microbiology
KHO	I	21 CFR 862.2560	Clinical Chemistry per regulation; Microbiology because it is used with the Sofia Strep A+ FIA

5.7. Predicate Device

Sofia Strep A+ FIA performed on Sofia

5.8. Device Description

The Sofia Strep A+ FIA involves the extraction of the antigenic components of the Group A Streptococcus (GAS) bacteria. The patient's Swab sample is placed in the Reagent Tube containing the Reagent Solution, during which time the bacterial antigens are extracted, making them more accessible to the specific antibodies. An aliquot of the extracted 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 Group A Streptococcal antigens are present, they will be bound by antibodies coupled to fluorescent microparticles that migrate through the

test strip. The fluorescent microparticles containing bound antigen will be captured by antibodies at a defined location on the test strip where they are detected by Sofia or Sofia 2. If antigens are not present, the fluorescent microparticles will not be trapped by the capture antibodies nor detected by Sofia or Sofia 2.

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 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 Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. All negative test results should be confirmed by either bacterial culture or an FDA-cleared molecular assay because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection.

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

5.10. Substantial Equivalence Information:

1. Predicate Device Name: Sofia Strep A+ FIA performed on Sofia
2. Predicate 510(k) Number: K141775
3. Comparison with Predicate:

Similarities and Differences		
Item	**Sofia Strep A+ FIA on Sofia**	**Sofia Strep A+ FIA on Sofia 2**
510(k) Number	**K141775**	**K171976**
Intended Use	The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection.	The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. All negative test results should be confirmed by either bacterial culture or an FDA-cleared molecular assay because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection. The Sofia Strep A+ 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	Walk Away Only	Read Now and Walk Away • 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.
Development Time	5 minutes for Sofia Strep A+ FIA	Same
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

Similarities and Differences		
Item	**Sofia Strep A+ FIA on Sofia**	**Sofia Strep A+ FIA on Sofia 2**
510(k) Number	**K141775**	**K171976**
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 Strep A+ 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 Strep A+ 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 five (5) to ten (10) minutes is acceptable.

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

e. Reproducibility
This study demonstrated intra- and inter-operator reproducibility and intra- and inter-laboratory reproducibility with a panel of test samples at various Group A Streptococcal antigen concentrations. This study also demonstrated comparable performance between Sofia and Sofia 2.

5.12. Conclusion

These studies demonstrated equivalent performance of the Sofia Strep A+ FIA on the Sofia and Sofia 2 analyzer.