Quidel Corporation
Xiaoxi Wang
Senior Regulatory Affairs Specialist
10165 McKellar Court
San Diego, California 92121

December 13, 2023

Re: K233688
Trade/Device Name: Sofia 2 SARS Antigen+ FIA; Sofia 2 SARS Antigen+ FIA Control Swab Set
Regulation Number: 21 CFR 866.3982
Regulation Name: Simple Point-Of-Care Device To Directly Detect SARS-Cov-2 Viral Targets From Clinical Specimens In Near-Patient Settings
Regulatory Class: Class II
Product Code: QVF
Dated: November 16, 2023
Received: November 17, 2023

Dear Xiaoxi Wang:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Silke Schlottmann -S

Digitally signed by Silke Schlottmann -S
Date: 2023.12.13 19:30:57 -05'00'

Silke Schlottmann, Ph.D.
Deputy Assistant Director
Bacteriology Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Sofia 2 SARS Antigen+ FIA (20405);
Sofia 2 SARS Antigen+ FIA Control Swab Set (20482)

Indications for Use *(Describe)*

Sofia 2 SARS Antigen+ FIA:
The Sofia 2 SARS Antigen+ FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 6 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Sofia 2 SARS Antigen+ FIA and followed up with a molecular test.

The test does not differentiate between SARS-CoV and SARS-CoV-2.

A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay.

Positive results do not rule out co-infection with bacteria or other viruses and should not be used as the sole basis for treatment or other patient management decisions.

Performanc characteristics for SARS-CoV-2 were established during the 2021-2022 SARS-CoV-2 pandemic when SARS CoV 2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary.

This test is intended for prescription use only and can be used in Point-of-Care settings.

Sofia 2 SARS Antigen+ FIA Control Swab Set:
The Sofia 2 SARS Antigen+ FIA Control Swabs are intended to be used as quality control samples with the Sofia 2 SARS Antigen+ FIA and are representative of positive and negative test samples. These Controls may be used to demonstrate that the reagents and assay procedure perform properly.

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."

510(k) Summary

Prepared on: 2023-11-16

Contact Details | 21 CFR 807.92(a)(1)

Applicant Name	Quidel Corporation
Applicant Address	10165 McKellar Court, San Diego, CA 92121, United States
Applicant Contact Telephone	619-679-4339
Applicant Contact	Ms. Xiaoxi Wang
Applicant Contact Email	xiaoxi.wang@quidelortho.com

Device Name | 21 CFR 807.92(a)(2)

Device Trade Name	Sofia 2 SARS Antigen+ FIA; Sofia 2 SARS Antigen+ FIA Control Swab Set
Common Name	Sofia 2 SARS Antigen+ FIA; Sofia 2 SARS Antigen+ FIA Control Swab Set
Classification Name	Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings
Regulation Number	21 CFR 866.3982
Product Code	QVF

Legally Marketed Predicate Device | 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
DEN220039	Sofia 2 SARS Antigen+ FIA; Sofia 2 SARS Antigen+ FIA Control Swab Set	QVF

Device Description Summary | 21 CFR 807.92(a)(4)

The Sofia 2 SARS Antigen+FIA is based upon a lateral flow technology that employs immunofluorescence technology in a sandwich design that is used with Sofia 2 to detect nucleocapsid protein from the SARS-CoV-2 virus in human anterior nasal swab specimens.

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. The Test Strip is composed of the following biochemical components dried and immobilized onto the nitrocellulose membrane: 1) sample pad that receives the specimen; 2) a label pad that contains detection fluorescent micro-particles, coated with monoclonal antibodies that are specific for SARS-CoV-2 nucleocapsid antigen; 3) embedded monoclonal antibodies specific for SARS-CoV-2 nucleocapsid antigen to capture the antigen-microparticle complex at the test line location. The sample pad facilitates migration of the sample fluid across the nitrocellulose strip into the absorbent pad (See Figure 4-1 in attachment). The test strip also contains a desiccant that does not participate in the assay but serves as a stabilizing agent during storage.

Sample is applied to in the sample well and migrates through a test strip, then passes through the test and control lines. If SARS-CoV-2 viral antigen is present, they will be bound by the fluorescent microparticles io the label pad region, forming an antigen-microparticle complex.

The test line is coated with monoclonal antibodies that are specific to SARS-CoV-2 nucleocapsid antigen and is intended to capture the antigen-microparticle complex. If SARS-CoV-2 viral antigen is not present, the fluorescent microparticles will not be trapped by the capture antibodies nor detected by Sofia 2.

The Sofia 2 SARS Antigen+ FIA employs antibody tagged microparticles dyed with a fluorescent compound, to be detected and read by the Sofia 2 reader instrument. The Sofia 2 analyzers automatically scan/image the test strip, collect and analyze the fluorescence data, and then calculate and report the result as either positive,

negative, or invalid.

Additionally, the Sofia 2 Antigen+ FIA utilizes a reference line for the Sofia 2 reader (to locate the test line and negative control line) and a procedural control (to assess for sample presence and adequate sample flow). No colored lines will be visible in the test window of the fluorescent assay cassette, thereby preventing visual interpretation of the test results. The operator must use the Sofia 2 analyzer to obtain a test result.

The Sofia 2 SARS Antigen+ FIA Control Swabs are intended to be used as quality control samples representative of positive and negative test samples, to demonstrate that the reagents are functional and that the assay procedure is correctly perform.

Intended Use/Indications for Use (Predicate Device)	**21 CFR 807.92(a)(5)**

Sofia 2 SARS Antigen+ FIA

The Sofia 2 SARS Antigen+ FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 6 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals when tested at least twice over three days with at least 48 hours between tests.

The test does not differentiate between SARS-CoV and SARS-CoV-2.

A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other patient management decisions.

Positive results do not rule out co-infection with other respiratory pathogens.

Performance characteristics for SARS-CoV-2 were established during the 2021-2022 SARS-CoV-2 pandemic when SARS CoV 2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary.

This test is intended for prescription use only and can be used in Point-of-Care settings.

Sofia 2 SARS Antigen+ FIA Control Swab Set

The Sofia 2 SARS Antigen+ FIA Control Swabs are intended to be used as quality control samples with the Sofia 2 SARS Antigen+ FIA and are representative of positive and negative test samples. These Controls may be used to demonstrate that the reagents and assay procedure perform properly.

Indications for Use Comparison		**21 CFR 807.92(a)(5)**
Device & Predicate Device(s):	K233688	DEN220039
Intended Use/Indications For Use	The Sofia 2 SARS Antigen+ FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 6 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals	The Sofia 2 SARS Antigen+ FIA is a lateral flow immunofluorescent sandwich assay that is used with the Sofia 2 instrument for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal swab specimens from individuals with signs and symptoms of upper respiratory infection (i.e., symptomatic) when testing is started within 6 days of symptom onset. The test is intended for use as an aid in the diagnosis of SARS-CoV-2 infections (COVID-19) in symptomatic individuals

	when either: tested at least twice over three days with at least 48 hours between tests; or when tested once, and negative by the Sofia 2 SARS Antigen+ FIA and followed up with a molecular test. The test does not differentiate between SARS-CoV and SARS-CoV-2. A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Positive results do not rule out co-infection with bacteria or other viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Performance characteristics for SARS-CoV-2 were established during the 2021-2022 SARS-CoV-2 pandemic when SARS CoV 2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary. This test is intended for prescription use only and can be used in Point-of-Care settings.	when tested at least twice over three days with at least 48 hours between tests. The test does not differentiate between SARS-CoV and SARS-CoV-2. A negative test result is presumptive, and it is recommended these results be confirmed by a molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other patient management decisions. Positive results do not rule out co-infection with other respiratory pathogens. Performance characteristics for SARS-CoV-2 were established during the 2021-2022 SARS-CoV-2 pandemic when SARS CoV 2 Omicron was the predominant SARS-CoV-2 variant in circulation. When other SARS-CoV-2 virus variant are emerging, performance characteristics may vary. This test is intended for prescription use only and can be used in Point-of-Care settings.

Technological Comparison	**21 CFR 807.92(a)(6)**
The Sofia 2 SARS Antigen + FIA was modified to include minor revisions to intended use statement on labeling. The proposed labeling modifications of the Sofia 2 SARS Antigen + FIA do not impact the device's substantial equivalence to the previously cleared version of this device. The device is as safe, as effective, and performs as well as the predicate device. The design, material, chemical composition, principle of operation are substantially equivalent to the predicate device.	

Non-Clinical and/or Clinical Tests Summary & Conclusions	**21 CFR 807.92(b)**
Not applicable.	