November 23, 2021

Quidel Corporation
Michelle Bodien
Director, Regulatory Affairs
10165 McKellar Court
San Diego, California 92121

Re: K211342
Trade/Device Name: Sofia 2 Campylobacter FIA
Regulation Number: 21 CFR 866.3110
Regulation Name: *Campylobacter fetus* Serological Reagents
Regulatory Class: Class I, reserved
Product Code: LQP, KHO
Dated: April 30, 2021
Received: May 3, 2021

Dear Michelle Bodien:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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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510(k) Summary

Submitter

Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
Telephone: (800) 874-1517

Submission Contact

Michelle Bodien
Director, Regulatory Affairs
(210) 740-5756

Date Prepared

November 22, 2021

Proprietary and Established Names

Sofia 2 Campylobacter FIA

Common Name

Campylobacter spp. rapid test

Classification

Product Code	Classification	Regulatory Section	Description
LQP	1	21 CFR 866.3110	*Campylobacter* spp.

Panel

Microbiology

Predicate Device

CAMPYLOBACTER QUIK CHEK™ (K191456)

Device Description

The Sofia 2 Campylobacter FIA employs immunofluorescence technology that is used with Sofia 2 for the rapid qualitative detection of *Campylobacter jejuni*, *Campylobacter coli*, *Campylobacter lari*, and *Campylobacter upsaliensis* specific antigens in fecal samples.

The patient's sample is placed in the Specimen Tube containing the Specimen Solution to dilute, making the antigenic components more accessible to the specific antibodies. An aliquot of the diluted sample is dispensed through a filter to remove particulates, making them more compatible for testing, into the Test Cassette sample well. From the sample well, the sample migrates through a test strip containing various unique chemical environments. If *Campylobacter jejuni*, *Campylobacter coli*, *Campylobacter lari*, or *Campylobacter upsaliensis* specific antigens are present, they will be bound by antibodies coupled to fluorescent microparticles that migrate through the test strip. The fluorescent microparticles containing bound proteins will be captured by antibodies at a defined location on the test strip where they are detected

by Sofia 2. If *Campylobacter jejuni*, *Campylobacter coli*, *Campylobacter lari*, or *Campylobacter upsaliensis* specific antigens are not present, the fluorescent microparticles will not be trapped by the capture antibodies nor detected by Sofia 2.

The Test Cassette is placed inside of Sofia 2 for automatically timed development (WALK AWAY Mode), or pre-incubated on the bench top prior to loading into Sofia 2 (READ NOW Mode), where Sofia 2 will scan, measure, and interpret the immunofluorescent signal using method-specific algorithms. Sofia 2 will display the test results (Positive, Negative, or Invalid) on the screen.

The fluorescence signal obtained with this assay is invisible to the unaided eye. The test results can only be obtained with the proper use of Sofia 2.

Intended Use

Sofia 2 Campylobacter FIA employs immunofluorescence for the rapid qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. Sofia 2 Campylobacter FIA is designed to detect *C. jejuni, C. coli, C. lari* and *C. upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.

Comparison with Predicate

Features	**Proposed Device** **Sofia 2 Campylobacter FIA**	**Predicate Device** ***CAMPYLOBACTER QUIK CHEK*™** **(K191456)**
Intended Use	Sofia 2 Campylobacter FIA employs immunofluorescence for the rapid qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. Sofia® 2 Campylobacter FIA is designed to detect *C. jejuni, C. coli, C. lari and C. upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.	The *CAMPYLOBACTER QUIK CHEK* test is a rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a *Campylobacter*-specific antigen in human fecal specimens. The *CAMPYLOBACTER QUIK CHEK* test is designed to detect *C. jejuni, C. coli, C. lari, and C. upsaliensis* from patients with signs and symptoms of gastroenteritis. The test is intended for use with preserved fecal specimens in transport media and unpreserved fecal specimens. Test results should be considered in conjunction with clinical findings and patient history.
Automated Analysis	Yes	No
Qualitative	Yes	Same
Analyte	*Campylobacter*-specific antigens (*C. jejuni, C. coli, C. lari* and *C. upsaliensis*)	Same

Features	Proposed Device Sofia 2 Campylobacter FIA	Predicate Device *CAMPYLOBACTER QUIK CHEK*™ (K191456)
Specimen Type	Human fecal specimens (unpreserved) or preserved in Cary Blair and C&S Transport Media	Same
Test Principle	Immunofluorescence device	Immunosorbent assay
Format	Lateral-flow test cassette	Membrane Enzyme Linked Immunosorbent Assay (ELISA)
Antibodies Used	Monoclonal and polyclonal antibodies that are specific to *Campylobacter* antigen	Same
External Controls	Test kit contains Positive (*Campylobacter*-specific antigen) and Negative Control Solutions	Same
Time to Result	15 minutes	<30 minutes
Storage	Room Temperature (15°C – 30°C)	Refrigerated (2°C – 8°C)

Performance Data

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate device. Key studies include the following:

Limit of Detection

The limit of detection (LoD) for Sofia 2 Campylobacter FIA was determined for four *Campylobacter* species in fecal matrix and in Cary Blair and C&S transport media. The LoD ranged from 9.82×10^4 to 5.21×10^6 colony forming units (cfu)/mL in fecal matrix, 1.57×10^5 to 5.21×10^6 cfu/mL in Cary Blair medium, and 1.50×10^5 to 2.71×10^6 cfu/mL in C&S medium (Table 1).

Table 1. Limits of Detection

Campylobacter Species	Minimum Detectable Limit*		
	Fecal Matrix	Cary Blair	C&S
	cfu/mL	cfu/mL	cfu/mL
C. jejuni	9.82×10^4	1.57×10^5	1.50×10^5
C. coli	1.15×10^6	1.59×10^6	9.02×10^5
C. lari	2.00×10^6	1.75×10^6	2.25×10^6
C. upsaliensis	5.21×10^6	5.21×10^6	2.71×10^6

cfu/mL = colony forming units per milliliter

*The levels of bacteria were determined by limiting dilution, bacterial culture, and colony counting to give cfu/mL.

Inclusivity (Analytical Reactivity)

Analytical reactivity for Sofia 2 Campylobacter FIA was demonstrated using 17 additional strains of *Campylobacter*, including clinical isolates. Each strain was spiked into negative fecal matrix at 2-3x the

LoD of the corresponding reference strain used to confirm the LoD. At 2-3x LoD, samples were at concentrations ranging from 2.95 x 10^5 to 1.44 x 10^7 colony forming units (cfu)/mL (Table 2).

Table 2. Analytical Reactivity

Campylobacter species	Strain	Level Detected*
Campylobacter jejuni	CCUG 6951	2.95 x 10^5 cfu/mL
	CCUG 12081	2.95 x 10^5 cfu/mL
	CCUG 29411	2.95 x 10^5 cfu/mL
	CCUG 38106	2.95 x 10^5 cfu/mL
Campylobacter jejuni subspecies *doylei*	CCUG 24567	2.95 x 10^5 cfu/mL
Campylobacter coli	CCUG 10956	3.45 x 10^6 cfu/mL
	CCUG 17755	3.45 x 10^6 cfu/mL
	CCUG36994	3.45 x 10^6 cfu/mL
	CCUG 53138	3.45 x 10^6 cfu/mL
Campylobacter lari	2015/2189	6.00 x 10^6 cfu/mL
	2015/1657	6.00 x 10^6 cfu/mL
	2015/2983	6.00 x 10^6 cfu/mL
	2016/1130H	6.00 x 10^6 cfu/mL
Campylobacter upsaliensis	2016/1950	1.44 x 10^7 cfu/mL
	2016/2826	1.44 x 10^7 cfu/mL
	2017/0349	1.44 x 10^7 cfu/mL
	2018/1669	1.44 x 10^7 cfu/mL

cfu/mL = colony forming units per milliliter

*The levels of bacteria were determined by limiting dilution, bacterial culture, and colony counting to give cfu/mL.

Additional inclusivity testing was performed for select strains of *C. coli*, *C. lari*, and *C. upsaliensis* to verify the lowest concentration of each strain that is reactive in the Sofia 2 Campylobacter FIA. Four-fold serial dilutions for each of the targeted strains were prepared from stock culture slurries using negative fecal matrix and tested in replicates of three in the assay. The qualitative results were used to determine the lowest detectable level in the series, where 3/3 results were positive (Table 3). The results demonstrated that these strains produced positive results in the assay at concentrations below the limit of detection established with the corresponding reference strains. Note: these results are not a true limit of detection and are used to demonstrate inclusivity of these strains at low concentrations of bacteria only.

Table 3. Dilution Testing – Inclusivity Strains

Species Tested	Dilution	Concentration (cfu/mL)	N	Pos	Neg	% Pos.
Campylobacter coli CCUG 53138 Stock 2.2 x 10^7 CFU/mL	Stock slurry	2.2 x 10^7	3	3	0	100
	1:4	5.5 x 10^6	3	3	0	100
	1:16	1.375 x 10^6	3	3	0	100
	1:64	3.438 x 10^5	3	3	0	100
	1:256	**8.594x 10^4**	**3**	**3**	**0**	**100**
	1:1024	2.148 x 10^4	3	0	3	0

Species Tested	Dilution	Concentration (cfu/mL)	N	Pos	Neg	% Pos.
	1:4096	5.371 x 10^3	3	0	3	0
Campylobacter lari 2015/2189 Stock 1.55 x 10^7 CFU/mL	Stock slurry	1.55 x 10^7	3	3	0	100
	1:4	3.875 x 10^6	3	3	0	100
	1:16	9.688 x 10^5	3	3	0	100
	1:64	2.422 x 10^5	3	3	0	100
	1:256	**6.055 x 10^4**	**3**	**3**	**0**	**100**
	1:1024	1.514 x 10^4	3	0	3	0
	1:4096	3.784 x 10^3	3	0	3	0
Campylobacter lari 2016/1130H Stock 1.4 x 10^7 CFU/mL	Stock slurry	1.4 x 10^7	3	3	0	100
	1:4	3.5 x 10^6	3	3	0	100
	1:16	8.75 x 10^5	3	3	0	100
	1:64	**2.188 x 10^5**	**3**	**3**	**0**	**100**
	1:256	5.469 x 10^4	3	0	3	0
	1:1024	1.367 x 10^4	3	0	3	0
	1:4096	3.418 x 10^3	3	0	3	0
Campylobacter upsaliensis 2016/1950 Stock 8.4 x 10^7 CFU/mL	Stock slurry	8.4 x 10^7	3	3	0	100
	1:4	2.1 x 10^7	3	3	0	100
	1:16	5.25 x 10^6	3	3	0	100
	1:64	**1.313 x 10^6**	**3**	**3**	**0**	**100**
	1:256	3.281 x 10^5	3	2	1	67
	1:1024	8.203 x 10^4	3	0	3	0
	1:4096	2.051 x 10^4	3	0	3	0

Cross Reactivity/Microbial Interference,

The cross reactivity of the Sofia 2 Campylobacter FIA was evaluated with a total of 48 bacterial and fungal microorganisms and 24 viral isolates. None of the microorganisms or viruses showed cross reactivity in the assay at the concentrations tested with the exception of *Campylobacter helveticus*. Additional *C. helveticus* concentrations were tested and cross-reactivity was no longer observed at 1.98x10^5 CFU/mL. For microbial interference testing, the same microorganisms and viruses were pre-mixed with *C. jejuni* at 2-3x LoD and tested in the assay. None showed any signs of microbial interference in the assay.

Interfering Substances

Several prescription and over-the-counter (OTC) products and endogenous substances were evaluated with the Sofia 2 Campylobacter FIA. Each substance was tested in the presence and absence of *C. jejuni* at 2-3x LoD. None of the substances interfered with the assay at the levels tested.

Specimen Storage and Stability

The results of this study demonstrated that neat, unpreserved fecal specimens were stable for up to 96 hours when stored refrigerated (2°C to 8°C) or at room temperature (15°C to 30°C) or up to 13 days when frozen (≤ -10°C) prior to use in the Sofia 2 Campylobacter FIA. Specimens stored in Thermo Scientific Protocol™ Cary Blair or Thermo Scientific Protocol™ C&S transport media were stable for up to 96 hours prior to use when refrigerated (2°C to 8°C) or at room temperature (15°C to 30°C).

An additional study determined that fecal specimens stored at -10°C are stable up to four freeze-thaw cycles prior to use in the Sofia 2 Campylobacter FIA.

Hook Effect / High Analyte Concentration

To ensure that a high concentration of *Campylobacter* antigen does not interfere with a positive reaction in the Sofia 2 Campylobacter FIA, high positive samples were prepared by spiking a negative fecal pool at a concentration possibly observed in clinical specimens. A total of 5 different dilutions of *C. jejuni, C. coli, C. lari,* and *C. upsaliensis* whole organism culture preparation, up to and including the clinically observed high concentration, were prepared and tested in triplicate. The results demonstrated that high analyte concentrations did not affect the detection of the antigen.

Precision

This study evaluated the within laboratory precision/repeatability of the Sofia 2 Campylobacter FIA at three (3) different levels of *C. jejuni* concentrations. Testing was performed for one (1) run per day and 4 replicates per run over twenty (20) non-consecutive days. A total of 240 replicates per level were tested (Table 4).

Table 4. Summary of Precision Qualitative Results

Lot	Concentration	# Negative	# Positive	Expected Result	Percent Agreement	95% C.I.
1	Negative	80	0	Negative	100%	95.4% to 100%
	1-2X C_{95}	0	80	Positive	100%	95.4% to 100%
	2-3X C_{95}	0	80	Positive	100%	95.4% to 100%
2	Negative	80	0	Negative	100%	95.4% to 100%
	1-2X C_{95}	0	80	Positive	100%	95.4% to 100%
	2-3X C_{95}	0	80	Positive	100%	95.4% to 100%
3	Negative	80	0	Negative	100%	95.4% to 100%
	1-2X C_{95}	0	80	Positive	100%	95.4% to 100%
	2-3X C_{95}	0	80	Positive	100%	95.4% to 100%

Reproducibility

The reproducibility of the Sofia 2 Campylobacter FIA was evaluated at 3 different laboratories using two product lots. Two different operators at each site tested a series of coded, contrived samples, prepared in negative clinical matrix, ranging from negative (no bacteria) to moderate positive (2-3 x LOD) levels of *C. jejuni*. Testing was conducted over 5 consecutive days. The inter-laboratory agreement (Table 5) for negative samples was 100% and 100% for positive samples.

Table 5. Reproducibility Study Inter- Laboratory Agreement

Site	Negative* (C_0)		High Negative* (0.5-1X C_5)		Low Positive** (1-2X C_{95})		Moderate Positive** (2-3X C_{95})	
	Lot 1	Lot 2	Lot 1	Lot 2	Lot 1	Lot 2	Lot 1	Lot 2
1	30/30	30/30	30/30	30/30	30/30	30/30	30/30	30/30
2	30/30	30/30	30/30	30/30	30/30	30/30	30/30	30/30
3	30/30	30/30	30/30	30/30	30/30	30/30	30/30	30/30
Total	**180/180**		**180/180**		**180/180**		**180/180**	
% Overall Agreement (95% CI)	**100% (97.9% to 100%)**		**100% (97.9% to 100%)**		**100% (97.9% to 100%)**		**100% (97.9% to 100%)**	

*Bacteria not detected/total
**Bacteria detected/total

Prospective Clinical Study

The performance of the Sofia 2 Campylobacter FIA was compared to culture and identification in a multi-center prospective clinical study. One hundred ninety-one (191) fresh, neat specimens and six hundred twenty (620) fresh specimens in transport media were evaluated. Sixty-two percent (62%) of the subjects were female and thirty-eight percent (38%) were male. Subjects ranged in age between 2 years to over 60 years. The results of the prospective clinical study are shown in Table 6. The eight (8) consensus positive specimens (Sofia Positive/ Culture Positive) were identified as *Campylobacter jejuni* by species-specific RT-PCR and bi-directional sequence analysis. Of the six (6) discordant specimens (Sofia Positive/ Culture Negative), three specimens were identified as positive for *C. jejuni*, two were *C. upsaliensis*, and one was *C. coli* by species-specific RT-PCR and bi-directional sequence analysis.

Table 6. Sofia 2 Campylobacter FIA Performance Compared to Culture with Fresh Specimens

	Culture		
	Pos	Neg	Total
Sofia Pos	8	6*	14
Sofia Neg	0	797	797
Total:	8	803	811

Sensitivity = 100% (8/8)
(95% CI=67.6% to 100%)

Specificity = 99.3% (797/803)
(95% CI=98.4% to 99.7%)

* Of the 6 culture negative – Sofia 2 Campylobacter FIA positive samples, all 6 were confirmed as positive by species-specific RT-PCR and bi-directional sequence analysis.

Archived Clinical Study

Seventy (70) frozen, characterized specimens were tested by the Sofia 2 Campylobacter FIA at a central laboratory including 35 culture-negative specimens preserved in transport media. Of the 35 positive specimens, there were a total of 11 specimens in transport media and 24 neat fecal specimens. The positive specimens were *Campylobacter* spp. culture-positive and were further characterized by RT-PCR and bi-directional sequencing to assess if weak positives were included in the archived study and determine performance of the Sofia 2 Campylobacter FIA with such specimens. All 35 specimens tested

positive for Campylobacter spp. by all methods, yielding 100% correlation with all test methods. Thirty specimens were identified as positive for *C. jejuni* and five were *C. coli*. Additionally, all 35 negative specimens yielded 100% correlation with all test methods.

Rare Isolates Testing

A study was conducted to evaluate the performance of the Sofia 2 Campylobacter FIA with less common analytes not represented during the clinical studies. Five (5) strains of each species of *C. coli*, *C. lari*, and *C. upsaliensis* were prepared at concentrations of 1-2 times the limit of detection of the corresponding reference strains in neat fecal matrix, fecal matrix in Cary Blair transport medium, and fecal matrix in C&S transport medium and tested in the assay over a period of three days. Each strain was detected by the assay with >90% positivity (Table 7). Additionally, a negative sample was prepared in each matrix and tested in parallel, and the expected negative results were obtained each day.

Table 7
Sofia 2 Campylobacter FIA Performance With Rare Isolates

Sample	Concentration Tested (CFU/mL)	n	Number of Negatives and Positives						% Positivity			
			Day 1		Day 2		Day 3		Day 1	Day 2	Day 3	Total
			# Neg	# Pos	# Neg	# Pos	# Neg	# Pos				
Fecal Matrix												
Negative	N/A	30	30	0	30	0	30	0	0	0	0	0
C. coli	2.30 x 10^6	30	0	30	0	30	0	30	100	100	100	100
C. lari	4.00 x 10^6	30	0	30	0	30	0	30	100	100	100	100
C. upsaliensis	9.58 x 10^6	30	0	30	0	30	0	30	100	100	100	100
Cary Blair												
Negative	N/A	30	30	0	30	0	30	0	0	0	0	0
C. coli	3.06 x 10^6	30	0	30	0	30	0	30	100	100	100	100
C. lari	3.50 x 10^6	30	1	29	0	30	0	30	97	100	100	99
C. upsaliensis	5.20 x 10^6	30	0	30	0	30	0	30	100	100	100	100
C&S												
Negative	N/A	30	30	0	30	0	30	0	0	0	0	0
C. coli	1.80 x 10^6	30	0	30	0	30	0	30	100	100	100	100
C. lari	2.50 X 10^6	30	0	30	0	30	0	30	100	100	100	100
C. upsaliensis	4.66 x 10^6	30	0	30	0	30	0	30	100	100	100	100