510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K171976

B. Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as K171976 and CW170009. CW170009 was submitted for CLIA Waiver of the Sofia Strep A+ FIA with the Sofia 2 analyzer.

To demonstrate equivalent performance of the Sofia Strep A+ FIA on the Sofia and Sofia 2 analyzers using elements of an assay migration study approach.

C. Measurand:

Group A β-hemolytic *Streptococcus* (GAS; *Streptococcus pyogenes*) antigens in throat swab specimens.

D. Type of Test:

The Sofia Strep A+ FIA is an immunofluorescence-based lateral flow *in vitro* diagnostic test for the qualitative detection of GAS antigens isolated from throat swab specimens obtained from symptomatic patients.

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Sofia Strep A+ FIA and Sofia 2

G. Regulatory Information:

1. Regulation Section:

   21 CFR 866.3740 - *Streptococcus spp.* Serological Reagents

2. Classification:

   Class I

3. Product Code(s):

GTY – Antigens, *Streptococcus spp.*, All Groups

KHO – Fluorometer, for Clinical Use

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended Use(s):

   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.

2. Indication(s) for Use:

   Same as intended use.

3. Special Conditions for Use Statement(s):

   For prescription use only

4. Special Instrument Requirements:

   To be used only with Sofia or Sofia 2 analyzers

I. Device Description:

1. Overview

   The Sofia Strep A+ FIA is a rapid lateral flow immunoassay for the qualitative detection of GAS antigens from throat swabs collected from patients with signs and symptoms of pharyngitis. The Sofia Strep A+ FIA components have not been modified; a detailed description of the lateral flow device is available in submission K141775, which describes Sofia Strep A+ FIA use with the original Sofia analyzer.

   The purpose of this submission is to obtain 510(k) clearance for the Sofia Strep A+ FIA for use with the newly developed Sofia 2 analyzer. The Sofia and Sofia 2 analyzers are similar in function and design. Both systems utilize the same fail-safes and failure alert

mechanisms, the same calibration and assay-specific cartridges, and the same ultraviolet light-emitting diodes (UV LEDs) to excite the fluorophore. The primary difference between the original Sofia and Sofia 2 analyzer is the design of the optical detection system. Sofia uses a motorized optics unit to collect fluorescent signal data as it performs a series of scans across the longitudinal axis of the test strip, whereas Sofia 2 captures a still image of the entire test strip window using a complimentary color-oxide semiconductor (CMOS) camera. To emulate Sofia, the Sofia 2 analyzer converts pixels captured by the CMOS camera to fluorescent signal data, which is analyzed in an equivalent manner to Sofia to yield qualitative test results.

2. Quality Control

   See Decision Summary for K141775.

3. Results Interpretation

   There are three possible test results for the Sofia Strep A+ FIA: 1) Positive for Strep A, 2) Negative for Strep A, and 3) Invalid. If an invalid test result is reported, the Sofia Strep A+ FIA should be repeated with a new patient sample and a new test cassette.

   Note: The Sofia and Sofia 2 analyzers may be set to one of two operating modes: "Walk Away" or "Read Now." Time to results for the Sofia and Sofia 2 analyzers are described below.

   - In Walk Away Mode, the user inserts the test cassette into the analyzer immediately following addition of the specimen to the Sofia Strep A+ FIA sample port. The analyzer automatically times the test development and provides positive or negative test results after 5 minutes.

   - In the Read Now Mode, the user incubates the test cassette on the benchtop for 5 minutes before inserting the cassette into the analyzer. Positive and negative test results are displayed within 1 minute.

   No changes were made to test components in the Sofia Strep A+ kits or calibration cassette.

J. Substantial Equivalence Information:

1. Predicate Device Name(s):

   Sofia Strep A+ FIA on Sofia analyzer

2. Predicate 510(k) Number:

   K141775

3. Comparison with Predicate:

Similarities and Differences		
	Predicate Device	**Proposed Device**
Item	**Sofia Strep A+ FIA on Sofia (K141775)**	**Sofia Strep A+ FIA on Sofia 2 (K171976)**
Regulation	866.3740	866.3740
Product code	GTY	GTY
Device class	I	I
Technology principle of operation	Lateral flow immunoassay	Same
Assay targets	GAS antigen	Same
Assay results	Qualitative	Same
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.
Specimen types	Throat swab	Same
Internal assay controls	procedural control zone and reference line	Same
External controls	Test kit contains positive and negative control swabs	Same
Instrument	Sofia	Sofia 2
Dimensions	24 cm x 16 cm x 10 cm	19.7 cm x 11.4 cm x 12.7cm
Weight	3 lbs	~2.5 lbs
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	External
Assay/instrument interface	Drawer	Same

Similarities and Differences		
	Predicate Device	**Proposed Device**
Item	**Sofia Strep A+ FIA on Sofia (K141775)**	**Sofia Strep A+ FIA on Sofia 2 (K171976)**
User interface	3.5 inch diagonal color LCD display and numeric keypad with function specific buttons touchscreen display	4 inch color LCD touchscreen display
Sample ID	External hand-held barcode scanner	Integrated barcode scanner
Cassette ID	Integrated barcode scanner	Integrated barcode scanner with custom 0.3MP camera
Development Modes	Walk Away only	Walk Away and Read Now
Time to obtain results	5 minutes	Same

K. Standard/Guidance Document Referenced (if applicable):

Not Applicable

L. Test Principle:

See decision summary for K141775. The FDA-cleared Sofia Strep A+ FIA has not been modified, and it is compatible with the newly developed Sofia 2 analyzer.

M. Performance Characteristics

Limit of Detection, Reproducibility, Assay Precision, Read Now vs Walk Away Mode, Analyzer Calibration, Transport Media/Sample Stability, and Method Comparison Studies were conducted to demonstrate equivalent performance of the Sofia Strep A+ FIA on the Sofia and Sofia 2 analyzers, where relevant. Results from each of these studies are described in sections *M(1a-1d)* and *M(2)* below. Additional analytical and clinical performance data for the Sofia Strep A+ FIA are available under K141775.

1. Analytical Performance

a. Limit of Detection

The limit of detection (LoD) of the Sofia Strep A+ FIA was established on both the Sofia and Sofia 2 analyzers. The study included three GAS strains spiked into negative clinical throat swab matrix. Briefly, dose-response curves were generated using three GAS strains from which the C95 concentration for each strain was interpolated. The preliminary LoD concentration was determined for each strain with two lots of cassettes on each instrument platform and defined as the lowest dilution yielding 100% positive results, where the next lower dilution returned one or more

negative results. The LoD was verified by testing each GAS strain to confirm that the expected proportion of positive results was obtained. An additional 60 replicates for each GAS strain were tested at the preliminary LoD on one cassette lot on each instrument platform. Testing spanned three days with at least 20 replicates run per day for each strain/instrument. The LoDs of the two instrument platforms were compared to demonstrate similar performance of the Sofia Strep A+ FIA with both analyzers.

Testing was performed in Read Now Mode in accordance with the Package Insert of Sofia Strep A+ FIA and user manuals of the two analyzers. A Calibration Check of each Sofia and Sofia 2 analyzer was performed prior to use on the first day of testing and the results were recorded. In addition, the External Positive and Negative Controls were tested with each cassette lot for every day of testing and on each analyzer used in the study. Results of control testing were recorded. The LoD and Signal/Cut-off (S/CO) results are shown in Table 1 below.

Table 1: Sofia Strep A+ FIA LoD Study Results on the Sofia and Sofia 2 Analyzers

Strain	Sofia		Sofia 2	
	LOD (CFU/test)	**S/CO**	**LOD (CFU/test)**	**S/CO**
Bruno	3.94E+04	1.71	4.07E+04	1.704
CDC-SS-1402	1.31E+05	1.93	1.60E+05	1.851
CDC-SS-1460	8.03E+04	1.65	7.45E+04	1.934

The established LoDs for the Sofia Strep A+ FIA on the Sofia and Sofia 2 analyzers with the 3 strains of GAS ranged from 3.94E+04 to 1.60E+05. The study confirmed that the LoD generated for the Sofia Strep A+ FIA on Sofia 2 is similar to the LoD generated on Sofia.

b. Reproducibility

Reproducibility of the Sofia Strep A+ FIA on the Sofia and Sofia 2 analyzers was evaluated at three different laboratories. A total of 270 samples were tested across 3 sites on both analyzers. Two operators at each site tested nine coded contrived samples (prepared in negative clinical matrix) from the reproducibility panel over 5 days per site. Test panels included Negative (no bacteria), Low Positive (1X LoD GAS), and Moderate Positive (2-3X LOD GAS) samples. The study demonstrated intra- and inter-laboratory reproducibility with a panel of GAS samples of various concentrations (See Table 2 and Table 3 below). When testing the low Strep A positive samples (C95), Sofia and Sofia 2 reported the samples positive 98.9% (89/90) of the time. When testing the moderately positive samples, Sofia and Sofia 2 called the Strep A+ sample positive 100% (90/90) of the time. Out of the 270 samples tested, there were no invalid test results obtained with either the Sofia or Sofia 2

analyzers. Studies were conducted in either Walk Away (225 data points) or Read Now Mode (45 data points) on both the Sofia and Sofia 2 analyzers.

Table 2. Qualitative Reproducibility Study Results Using the Sofia Analyzer

Site	Operator	Negative	Strep A Low Positive (1X LoD)	Strep A Moderate Positive (2-3X LoD)
1	1	15/15	15/15	15/15
	2	15/15	14/15	15/15
2	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
3	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
Combined Total		90/90	89/90	90/90
Percent Agreement (95% CI)		100% (95.9-100%)	98.9% (94.0-99.9%)	100% (95.9-100%)

Table 3. Qualitative Reproducibility Study Results Using the Sofia 2 Analyzer

Site	Operator	Negative	Strep A Low Positive (1X LoD)	Strep A Moderate Positive (2-3X LoD)
1	1	15/15	15/15	15/15
	2	15/15	14/15	15/15
2	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
3	1	15/15	15/15	15/15
	2	15/15	15/15	15/15
Combined Total		90/90	89/90	90/90
Percent Agreement (95% CI)		100% (95.9-100%)	98.9% (94.0-99.9%)	100% (95.9-100%)

The quantitative results reported in terms of Signal/Cut-off (S/CO) for the Reproducibility Study are shown below in Table 4 for the Sofia analyzer and Table 5 for the Sofia 2 analyzer. The mean, standard deviation (SD) and the percent coefficient of variation (%CV) are provided for each of the panel members by site and overall average.

Table 4. S/CO-based Reproducibility Results Using the Sofia Analyzer

Site	Sofia Analyzer								
	Negative			Strep A Low Positive			Strep A Moderate Positive		
	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
1	0.238	0.077	32.3	2.528	0.749	29.6	8.424	3.479	41.3
2	0.235	0.079	33.4	3.317	1.001	30.2	11.186	3.657	32.7
3	0.229	0.101	44.0	3.047	0.699	22.9	10.424	2.397	23.0
Avg	0.234	0.085	36.4	2.964	0.882	29.7	10.011	3.396	33.9

Table 5. S/CO-based Reproducibility Results Using the Sofia 2 Analyzer

Site	Sofia 2 Analyzer								
	Negative			Strep A Low Positive			Strep A Moderate Positive		
	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
1	0.229	0.092	40.2	2.639	1.058	40.1	9.214	3.717	40.3
2	0.218	0.114	52.4	3.635	1.388	38.2	12.688	4.319	34.0
3	0.226	0.131	58.0	3.577	0.877	24.5	12.100	3.535	29.2
Avg	0.224	0.112	50.1	3.284	1.205	36.7	11.334	4.121	36.4

Any quantitative differences between sites did not impact the final qualitative results reported.

c. Assay Precision

To supplement the Reproducibility Study, within-laboratory precision of the Sofia and Sofia 2 analyzers was evaluated. The precision of Sofia and Sofia 2 analyzers with the Sofia Strep A+ FIA was examined using three lots of devices and two operators testing the same samples for twelve (12) days over two calibration cycles for a total of 144 data points for each analyzer and each sample type. One strain of GAS was tested at Low Positive (approximately 1X LoD) and Moderate Positive (approximately 2-3X LoD) levels. A Negative sample was also included in the test panel.

One Sofia and two Sofia 2 analyzers (one for back-up) were used in this study. When an error for saving the test result happened on the Sofia 2 analyzer, the cassette was re-scanned immediately on the backup Sofia 2 analyzer. The testing was conducted in Read Now Mode. Overall percent agreement between the expected results and the precision study results for the Sofia and Sofia 2 analyzers is shown in Table 6 below. The qualitative call rates for both Sofia and Sofia 2 analyzers were the same for the Negative, Low Positive and Moderate Positive samples: 100% negative for the Negative samples and 100% positive for the Low and Moderate Positive samples. There were three (3) invalid tests reported in the study.

Table 6. Qualitative Precision Study Results Summary

Sample Type	Sofia		Sofia 2	
	Overall Agreement	% Overall Agreement	Overall Agreement	% Overall Agreement
Negative	144/144	100	144/144	100
Low Positive (1X LoD)	144/144	100	144/144	100
Moderate Positive (2-3X LoD)	144/144	100	144/144	100

For each of the sample types listed above, the mean S/CO, standard deviation (SD), and percent coefficient of variation (%CV) were calculated. Results for samples tested using the Sofia and Sofia 2 analyzers are shown in Table 7.

Table 7. S/CO-based Precision Study Results Summary

Platform	Sample Type	Mean S/CO	SD	% CV
Sofia	Negative	0.25	0.07	26.6%
	Low Positive (1X LoD)	2.88	0.81	28.0%
	Moderate Positive (2-3X LoD)	13.95	4.38	31.4%
Sofia 2	Negative	0.24	0.07	30.2%
	Low Positive (1X LoD)	2.88	0.81	27.9%
	Moderate Positive (2-3X LoD)	14.21	4.96	34.9%

Overall, the study results showed that Sofia and Sofia 2 analyzers generated equivalent qualitative overall agreement results when used by multiple operators and operated over multiple days.

d. Read Now vs Walk-Away Mode/Temperature Study

The purpose of this study was to document testing results of the Sofia Strep A+ FIA in Read Now and Walk Away Modes on the Sofia 2 analyzer. In the Read Now Mode, the cassette with loaded sample was developed for 5 minutes on the bench top before insertion into the Sofia 2 analyzer for scanning. In Walk Away Mode, the cassette was placed in the Sofia 2 analyzer immediately and developed for 5 minutes in the Sofia 2 analyzer. Additionally, testing was performed at different ambient temperatures. The entire test kit (including the Sofia 2 analyzer) was equilibrated to, and tested at, each of the following environmental conditions: 15°C, room temperature, and 30°C. The temperature range evaluated was the same as the range currently approved for the Sofia Strep A+ FIA and the existing Sofia analyzer.

For sample testing, one GAS strain was tested at approximately 2-3X LoD. Contrived Negative Matrix was also tested as the negative sample. All positive and negative samples were in 100% agreement with the expected results regardless of the temperature and reading mode. This study demonstrated that the correct results can be obtained with the Sofia Strep A+ FIA when the test materials are stored and tested at temperatures from 15° to 30°C in both Read Now and Walk Away Modes on Sofia 2 analyzer.

e. Analyzer Calibration

The purpose of this study was to assess the Sofia 2 intra-instrument variability and performance during the maximum 30-day calibration cycle. To verify the intra-instrument variability, the study was executed using five Sofia 2 analyzers. On day 1, all analyzers were calibrated. The variability in RFU for each of the four (4) lines was analyzed by each instrument to determine the percentage change in RFU over three reads per working day for 45 calendar days. The study data showed that the Sofia 2 analyzer demonstrated intra-instrument variability of less than 6% (+/-3%) over the maximum calibration interval of 30 days, and therefore, met the acceptance specification over this interval.

f. Transport Media and Sample Stability

The purpose of this study was to evaluate the stability of GAS spiked on

- Puritan Rayon Swabs stored in a transport tube with a secured cap
- BBL Culture Swabs stored in the Collection and Transport system containing Stuart's media

The study included testing the contrived swab specimens spiked on Puritan Rayon swabs stored in dry transported tubes with secured caps as well as spiked on BBL Culture Swabs stored in the Collection and Transport system for up to 50 hours at two different temperatures. The seeded swabs were stored and kept at 4°C for 0, 6, 24, 48 and 50 hours and room temperature for 0, 6, 24, 48 and 50 hours. Six (6) replicates for each condition were tested. The cassettes were read in Read Now Mode on the Sofia and Sofia 2 analyzers.

When the negative matrix was tested with BBL CultureSwab and Dry Puritan Rayon swabs after storage at room temperature and at 2-8°C on Sofia and Sofia 2 analyzers, all valid negative swabs were negative and yielded 100% negativity up to 50 hours. There was one (1) invalid result. When the positive samples were tested with BBL CultureSwab and Dry Puritan Rayon swabs after storage at room temperature and at 2-8°C on Sofia and Sofia 2 analyzers, all swabs were positive and yielded 100% positivity up to 50 hours. There were three (3) invalid tests. If not processed soon after collection, Quidel has stated that swabs can be held in any clean, dry plastic tube or sleeve up to 24 hours at room temperature (23°C) or refrigerated (2°C to 8°C) up to 48 hours. For the BBL CultureSwab with Liquid Stuart Media, the recommended storage is 2-8°C or ambient temperature up to 48 hours.

2. Comparison Studies

a. Method Comparison

A multi-center study was conducted to evaluate the performance of the Sofia Strep A+ FIA run on the Sofia 2 analyzer vs the Sofia analyzer using a panel of known positive and negative clinical and contrived samples prepared in clinical negative matrix. One-hundred (100) Strep A positive and (100) Strep A negative samples were incorporated into each panel (tested positive or negative with the current FDA-cleared Sofia Strep A+ FIA on Sofia). According to the test protocol, positive panel members were prepared so that approximately 60% to 80% of the samples had Strep A levels close to the Sofia Strep A+ FIA cut-off with approximately one-half around the LoD and the remainder as moderate positive samples. The remaining positive samples were evenly distributed across the range of the assay. Negative panel members were prepared so that approximately 30% to 40% were High Negatives.

Each panel member was assigned to one of the analyte concentration levels based on the signal-to-cut off ratio (S/CO) that was obtained from testing on the Sofia analyzer. Table 8 below shows the S/CO for each level.

Table 8. S/CO Target Values

Panel Member	GAS S/CO
Negative	<0.5
High Negative	0.55-0.99
Low Positive (1X LoD)	1.1-2.4
Moderate Positive (2-3X LoD)	3.0-6.0
High Positive (4-5X LoD)	6.1-9
Very High Positive (>5X LoD)	>10.3

The final composition of the Method Comparison Panel was reported as shown in Table 9 below.

Table 9. Method Comparison Panel

Panel Member	Quantity per panel
Negative	70
High Negative	30
Low Positive (1X LoD)	30
Moderate Positive (2-3X LoD)	36
High Positive (4-5X LoD)	19
Very High Positive (>5X LoD)	15

All samples were coded and used to prepare randomized panels, with an identical panel of specimens prepared for each of three sites. Each site received a set of two hundred (200) numbered tubes each containing 2 swabs, as well as Positive and Negative Control swabs. For all analyte levels combined, the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) values between the Sofia

and the Sofia 2 results were 98.7% and 96.9%, respectively (See Table 10 below). Agreement between the results obtained on the Sofia and Sofia 2 analyzers for each of the individual analyte levels tested is shown in Table 11 below.

There were 12 discordant results for GAS across all three sites. Ten discordant samples were categorized as "*High Negative*" samples, and two discordant samples were characterized as "*Negative"* samples. For the two discordant samples originally prepared as *"Negative"* samples, results were reported as positive by the Sofia analyzer but negative by the Sofia 2 analyzer. The two false positives by the Sofia analyzer appeared to be due to contamination of the samples. Discordant results were observed across all three sites and were generated by multiple operators; there was no trend indicating any instrument bias.

Table 10. Method Comparison Study of GAS Results for the Sofia and Sofia 2 Analyzers

	Sofia Positive	**Sofia Negative**	**Total**
Sofia 2 Positive	369	7[b]	376
Sofia 2 Negative	5[a]	219	224
Total	374	226	600
	PPA: 98.7% (369/374), 95% CI: (96.9%-99.4%) NPA: 96.9% (219/226), 95% CI: (93.7%-98.5%)		

[a] *There were 5 discordant Sofia 2 negative/Sofia positive results for Strep A, which included 3 high negative (C5) and 2 true negative (C0) specimens. The 2 true negatives (C0) showing false positive results in Sofia appeared to be due to contamination.*

[b] *There were 7 discordant Sofia 2 positive/Sofia negative results for Strep A, which included all high negative (C5) specimens.*

Table 11: Agreement Stratified by GAS Level

Analyte Level	Qualitative Method Comparison Results		
		Sofia Positive	Sofia Negative
Negative	Sofia 2 Positive	0	0
	Sofia 2 Negative	2*	208
High Negative	Sofia 2 Positive	69	7
	Sofia 2 Negative	3	11
Low Positive (1X LoD)	Sofia 2 Positive	90	0
	Sofia 2 Negative	0	0
Moderate Positive (2-3X LoD)	Sofia 2 Positive	108	0
	Sofia 2 Negative	0	0
High Positive (4-5X LoD)	Sofia 2 Positive	57	0
	Sofia 2 Negative	0	0
Strong Positive (>5X LoD)	Sofia 2 Positive	45	0
	Sofia 2 Negative	0	0

**Documented as operator error (potential contamination)*

The Method Comparison Study results demonstrated that the performance of the Sofia Strep A+ FIA on the Sofia 2 analyzer was comparable to the Sofia analyzer (predicate device).

N. Instrumentation/System Description

1. Instrument Name:

   Sofia and Sofia 2 analyzers

2. System Description:

   The Sofia instruments are equipped with UV LED lighting and optical detection systems that are designed to collect and analyze fluorescent data emitted from the Sofia Strep A+ FIA test cassettes. The instrument software contains embedded assay-specific algorithms that are used to convert the fluorescent signal data into a qualitative test result.

3. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.

   Yes __X__ or No _____

4. Level of Concern

   Moderate

5. Software Description

   The Sofia 2 analyzer images the test strip and utilizes an embedded software algorithm to process the resulting data set into a qualitative test result. A positive test result for the analyte is determined by detection and analysis of the fluorescent signal at the test and reference lines, which are processed by the assay-specific algorithm. The algorithm employs a smoothing filter to the data and, identifies a peak maxima, minima and width, then calculates the RFU value based on peak height for the analyte test line. Results are presented on a screen and can be printed on an integrated printer.

6. Specimen Identification

   Each cassette is labeled with a barcode that is detected by the Sofia 2 internal barcode reader. The 2-dimensinal barcode contains lot, expiration, and test method information. If the cassette is not in the correct orientation, the barcode cannot be read and the analyzer will display an error.

7. Calibration

   To ensure that signal drift is controlled, the Sofia 2 analyzer has a calibration algorithm that reminds the operator to check the calibration status of the instrument every 30 days. The calibration cassette uses a highly stable fluorescent reagent along with a unique barcode. The insertion of this cassette triggers the Sofia 2 analyzer to self-check its calibration.

O. Other supportive Instrument Characteristics Data Not Covered in the "Performance Characteristics" Section Above

N/A

P. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Q. Conclusion

The submitted information in the premarket notification is complete and supports a substantial equivalence decision.