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

QUIDEL CORPORATION
JOHN TAMERIUS
SENIOR VICE PRESIDENT, CLINICAL AND REGULATORY
12544 HIGH BLUFF (ADMINISTRATIVE OFFICE LOCATION)
SAN DIEGO CA 92130

December 16, 2014

Re: K141775
Trade/Device Name: Sofia® Strep A+ FIA
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus spp.* serological reagents
Regulatory Class: I
Product Code: GTY
Dated: June 30, 2014
Received: July 1, 2014

Dear Dr. Tamerius:

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,

Uwe Scherf -S for

Sally A. Hojvat, 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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k141775

Device Name
Sofia® Strep A+ FIA Assay

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 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

Submitted By:	Quidel Corporation 12544 High Bluff Drive, Suite 200 (Administrative Offices) San Diego, California 92130 Telephone: 858-552-7908 Fax: 858-646-8045
Submission Contact:	John D. Tamerius, Ph.D.
Date Prepared:	June 30, 2014
Device Trade Name:	Sofia® Strep A+ FIA and Sofia
Common Name:	Strep A immunological test system and Fluorometer
Predicate Devices:	Sofia Strep A FIA for use with Sofia, K123793
Device Classification/Name:	21 CFR 866.3740 / Streptococcus Group A serological reagents
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.
Physiologic Basis of the Test:	Group A Streptococcus is one of the most common causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications such as rheumatic fever and glomerulonephritis. Conventional procedures for identification of Group A Streptococcus from throat swabs involve the culture, isolation, and subsequent identification of viable pathogen at 24 to 48 hours or longer for results.

Device Description:

The Sofia Strep A FIA employs immunofluorescence technology that is used with the Sofia analyzer (Sofia) to detect Group A Streptococcal antigen.

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 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. If antigens are not present, the fluorescent microparticles will not be trapped by the capture antibodies nor detected by Sofia.

Note: The Cassette, now containing the sample, is placed directly inside Sofia for automatically timed development (WALK AWAY Mode).

Sofia scans, measures, and interprets the immunofluorescent signal using method-specific algorithms. Sofia 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, or transmitted via an LIS connection.

Device Comparison:

Note: The **shaded cells** in Table 1 below identify where there are differences between the proposed and predicate devices.

Table 1

Item	Proposed Device	Predicate Device
Features	**Sofia Strep A+ FIA with Sofia**	**Sofia Strep A FIA with Sofia**
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 employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs of symptomatic patients. 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.
FDA File Number	k141775	K123793
Manufacturer	Quidel Corporation and LRE	Quidel Corporation and LRE
Regulation Number	21 CFR 866.3740 and 21 CFR 866.2560	21 CFR 866.3740 and 21 CFR 866.2560
Classification Product Code	GTY and KHO	GTY and KHO
Instrument	Sofia	Sofia
Analyte	Group A Streptococcus	Group A Streptococcus
Automated Analysis	Yes	Yes
Mode(s)	Walk-Away only	Read-Now and Walk-Away
Read Results	Read results on instrument screen or print with optional printer	Read results on instrument screen or print with optional printer
Calibrator	Yes – Calibration Cassette and QC Card provided	Yes – Calibration Cassette and QC Card provided
Read Result Time	5 Minutes	5 Minutes
Specimen Types	Throat swab	Throat swab
Qualitative	Yes	Yes
Test Principle	Immunofluorescence Device	Immunofluorescence Device

Item	Proposed Device	Predicate Device
Features	**Sofia Strep A+ FIA with Sofia**	**Sofia Strep A FIA with Sofia**
Format	Lateral-flow Test Cassette	Lateral-flow Test Cassette
Antibodies Used	Polyclonal rabbit antibodies that are specific to Group A Streptococcus	Polyclonal rabbit antibodies that are specific to Group A Streptococcus
Detection Particle	Polystyrene microparticles dyed with Europium chelate	Polystyrene microparticles dyed with Europium chelate
Storage	Room Temperature	Room Temperature
Reagent Solution	One reagent bottle containing sodium nitrite and hydrochloric acid in glass ampoule	One reagent bottle containing sodium nitrite and acetic acid in glass ampoule
Transfer Device	Fixed volume pipette used to transfer patient sample mixed with reagent into Test Cassette	Fixed volume pipette used to transfer patient sample mixed with reagent into Test Cassette
External Controls	Test kit contains Positive and Negative Control Swabs	Test kit contains Positive and Negative Control Swabs
Quality Control Features	Built-in features include: • Built-in procedural control zone scanned by the analyzer to determine whether adequate flow occurred • Analyzer prevents used or expired cartridge from being read by the reader • Cassette properly inserted	Built-in features include: • Built-in procedural control zone scanned by the analyzer to determine whether adequate flow occurred • Analyzer prevents used or expired cartridge from being read by the reader • Cassette properly inserted

Summary of Performance Data:

Sofia Strep A+ FIA Performance vs. Cell Culture and vs. Cell Culture Resolved by PCR
The performance of the Sofia Strep A+ FIA was compared to standard bacterial culture and identification and an FDA-cleared Group A Streptococcus RT-PCR assay in a multi-center clinical field study. This study was conducted by untrained health care personnel during 2014 at 7 distinct CLIA-waived sites in various geographical regions within the United States. In this multi-center, point-of-care (POC) field trial, two (2) throat swabs were collected from eight hundred fifty-one (851) patients with symptoms suggestive of bacterial pharyngitis.

One throat swab was tested fresh at the CLIA-waived site in the Sofia Strep A+ FIA. A second swab was placed into transport medium and transported on cold ice packs to a central Reference Laboratory. The swab was streaked on a sheep blood agar plate (SBA) and cultured for up to 48 hours. A portion of the transport medium was subsequently tested in the PCR assay. The performance of the Sofia Strep A+ FIA was determined by comparison of the rapid FIA test result to the corresponding culture result (Table 2).

Table 2
Sofia Strep A+ FIA Performance Compared to Culture

	Culture	
	Pos	Neg
Sofia Pos	164	38*
Sofia Neg	11**	638
Total:	175	676

Sensitivity = 93.7% (164/175) (95%CI=89.1%-96.5%)
Specificity = 94.4% (638/676) (95% CI=92.4%-95.9%)
PPV = 81.2% (164/202)
NPV = 98.3% (638/649)

*Of the 38 discordant specimens, 24 of these specimens were positive for GAS when tested with an FDA-cleared molecular device, 14 were negative.
**Of the 11 discordant specimens, 3 were negative when tested with an FDA-cleared molecular device, 8 were positive.

Reproducibility Studies
The reproducibility of the Sofia Strep A+ FIA was evaluated at 3 different laboratories. 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 (3 x LoD) Group A Streptococcus. The inter-laboratory agreement (Table 3) for negative samples was 90-100% and 87-100% for positive samples. The intra-laboratory agreement (Table 4) for all samples ranged from 93-95%.

Table 3
Sofia Strep A+ FIA Reproducibility Study Inter-laboratory Agreement

Site	Negative* (C_0)	High Negative* (C_5)	Low Positive** (C_{95})	Mod Positive** (C_{100})
1	30/30	27/30	27/30	30/30
2	30/30	29/30	23/30	30/30
3	30/30	25/30	28/30	30/30
Total	90/90	81/90	78/90	90/90
% Overall Agreement (95% CI)	**100% (95.9-100.0%)**	**90% (82.1-94.7%)**	**87% (78.1-92.2%)**	**100% (95.9-100.0%)**

*Bacteria not detected/total

**Bacteria detected/total

Table 4
Sofia Strep A+ FIA Reproducibility Study Intra-laboratory Agreement

Site	Negative* (C_0)	High Negative* (C_5)	Low Positive** (C_{95})	Mod. Positive** (C_{100})	% Overall Agreement (95% CI)
1	30/30	27/30	27/30	30/30	**95%** (114/120) **(89.5-97.7%)**
2	30/30	29/30	23/30	30/30	**93%** (112/120) **(87.4-96.6%)**
3	30/30	25/30	28/30	30/30	**94%** (113/120) **(88.5-97.2%)**

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

Limit of Detection
The limit of detection (LoD) for the Sofia Strep A+ FIA was determined using 3 strains of Group A *Streptococcus pyogenes.* The LoD ranged from 2.76E+03 to 8.13E+03 colony forming units (cfu)/test (Table 5).

Table 5
Sofia Strep A+ FIA Limits of Detection

Strain	Minimum Detectable Level*
Bruno [CIP 104226]	4.00E+03 cfu/test
CDC-SS-1402	8.13E+03 cfu/test
CDC-SS-1460	2.76E+03 cfu/test

cfu/test = colony forming units/test

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

Analytical Reactivity

Analytical reactivity for the Sofia Strep A+ FIA was demonstrated using 21 strains of Group A *Streptococcus pyogenes* tested at 1.74E+04 colony forming units (cfu)/test (Table 6).

Table 6
Analytical Reactivity

***Streptococcus pyogenes* Strain**
Strain #1 (ATCC-19615)
Strain #2 (ATCC-700942)
Strain #3 (ATCC-700952)
Strain #4 (Clinical Isolate-52123)
Strain #5 (Clinical Isolate-52120)
Strain #6 (Clinical Isolate-62055)
Strain #7 (Clinical Isolate-52152)
Strain #8 (Clinical Isolate-62092)
Strain #9 (Clinical Isolate-52151)
Strain #10 (ATCC-700482)
Strain #11 (ATCC-BAA-1315)
Strain #12 (ATCC-700459)
Strain #13 (ATCC-12203)
Strain #14 (ATCC-700944)
Strain #15 (Clinical Isolate-52154)
Strain #16 (Clinical Isolate-5036)
Strain #17 (Clinical Isolate-5095)
Strain #18 (Clinical Isolate-5017)
Strain #19 (Clinical Isolate-5060)
Strain #20 (Clinical Isolate-5112)
Strain #21 (Clinical Isolate-5008)

Analytical Specificity

Cross Reactivity

The cross reactivity of the Sofia Strep A+ FIA was evaluated with a total of 61 non-Group A Streptococcus bacterial and fungal microorganisms, and 26 viral isolates. None of the microorganisms or viruses listed below in Table 7 showed any sign of cross reactivity in the assay. The same microorganisms and viruses in Table 7 were pre-mixed with Group A Strep and tested in the Sofia Strep A+ FIA.

Table 7
Cross Reactivity

Organism/Virus	**Test Concentration****
Arcanobacterium haemolyticum	3.00E+05 cfu/test
Bacteroides fragilis	3.00E+07 cfu/test
Bordetella pertussis	3.00E+07 cfu/test
Candida albicans	3.00E+04 cfu/test
Corynebacterium diphtheriae	3.00E+05 cfu/test
*Corynebacterium pseudodiphtheriticum**	3.00E+06 cfu/test
*Enterococcus faecalis**	1.40E+06 cfu/test

Organism/Virus	Test Concentration**
Enterococcus faecium	3.00E+06 cfu/test
Escherichia coli	1.50E+07 cfu/test
Fusobacterium necrophorum	3.00E+06 cfu/test
Haemophilus influenzae	3.00E+07 cfu/test
Haemophilus parahaemolyticus	3.00E+06 cfu/test
Klebsielle pneumoniae	3.00E+07 cfu/test
Moraxella catarrhalis	3.00E+06 cfu/test
Neisseria gonorrhoeae	3.00E+06 cfu/test
Neisseria lactamica	3.00E+06 cfu/test
Neisseria meningitidis	3.00E+06 cfu/test
Neisseria sicca	3.00E+07 cfu/test
Neisseria subflava	3.00E+07 cfu/test
Proteus vulgaris	3.00E+07 cfu/test
Pseudomonas aeruginosa	3.00E+06 cfu/test
Serratia marcescens	3.00E+07 cfu/test
*Staphylococcus aureus**	3.00E+06 cfu/test
Staphylococcus epidermidis	3.00E+06 cfu/test
Staphylococcus haemolyticus	3.00E+05 cfu/test
Staphylococcus intermedius	3.00E+05 cfu/test
Staphylococcus saprophyticus	3.00E+06 cfu/test
Streptococcus anginosus	3.00E+06 cfu/test
Streptococcus gordonii	3.00E+04 cfu/test
Streptococcus mitis	3.00E+04 cfu/test
*Streptococcus mutans**	3.00E+06 cfu/test
Streptococcus oralis	3.00E+06 cfu/test
*Streptococcus parasanginis**	3.00E+06 cfu/test
Streptococcus pneumoniae	3.00E+06 cfu/test
Streptococcus salivaris	3.00E+05 cfu/test
Streptococcus sanguinis	3.00E+06 cfu/test
Streptococcus Group B Strain #1: *Streptococcus agalactiae*	3.00E+06 cfu/test
Streptococcus Group B Strain #2	3.00E+06 cfu/test
Streptococcus Group B Strain #3	3.00E+06 cfu/test
Streptococcus Group B Strain #4	3.00E+06 cfu/test
Streptococcus Group B Strain #5	3.00E+06 cfu/test
Streptococcus Group C Strain #1	3.00E+06 cfu/test
Streptococcus Group C Strain #2	3.00E+06 cfu/test
Streptococcus Group C Strain #3	3.00E+06 cfu/test
Streptococcus Group C Strain #4: *Streptococcus dysgalactiae**	3.00E+06 cfu/test

Organism/Virus	Test Concentration**
Streptococcus Group C Strain #5	3.00E+05 cfu/test
Streptococcus Group D Strain #1: *Enterococcus casseliflavus*	3.00E+06 cfu/test
Streptococcus Group D Strain #2	3.00E+06 cfu/test
Streptococcus Group D Strain #3*	3.00E+06 cfu/test
Streptococcus Group D strain #4: *Enterococcus faecalis*	3.00E+06 cfu/test
Streptococcus Group D strain #5: *Enterococcus faecalis*	3.00E+06 cfu/test
Streptococcus Group F Strain #1	1.00E+05 cfu/test
Streptococcus Group F Strain #2	3.00E+06 cfu/test
Streptococcus Group F Strain #3	1.00E+06 cfu/test
Streptococcus Group F Strain #4*	3.00E+05 cfu/test
Streptococcus Group F Strain #5	3.00E+05 cfu/test
Streptococcus Group G strain #1: *Streptococcus dysgalactiae*	3.00E+07 cfu/test
Streptococcus Group G Strain #2	3.00E+06 cfu/test
Streptococcus Group G Strain #3	3.00E+06 cfu/test
Streptococcus Group G Strain #4	3.00E+06 cfu/test
Streptococcus Group G Strain #5	3.00E+06 cfu/test
Adenovirus Type 1*	3.00E+11 $TCID_{50}$/test
Adenovirus Type 3*	3.00E+05 $TCID_{50}$/test
Adenovirus Type 4	7.50E+03 $TCID_{50}$/test
Adenovirus Type 5	3.00E+05 $TCID_{50}$/test
Adenovirus Type 11	3.00E+04 $TCID_{50}$/test
Coronavirus 229E	3.00E+04 $TCID_{50}$/test
Coronavirus OC43	3.00E+04 $TCID_{50}$/test
Coxsackievirus B5 (Faulkner)	3.00E+06 $TCID_{50}$/test
Cytomegalovirus (Towne)	3.00E+03 $TCID_{50}$/test
Echovirus Type 3	1.50E+04 $TCID_{50}$/test
Epstein Barr Virus (EBV)*	3.00E+07 genome copies/test
Herpes Simplex Virus 1	3.00E+04 $TCID_{50}$/test
Herpes Simplex Virus 2	3.00E+04 $TCID_{50}$/test
Influenza A/New Jersey/8/76 (H1N1)	3.00E+04 $TCID_{50}$/test
Influenza A/Victoria/3/75 (H3N2)	3.00E+04 $TCID_{50}$/test
Influenza B/Hong Kong/5/72	3.00E+04 $TCID_{50}$/test
Influenza B/Panama/45/90	1.50E+04 $TCID_{50}$/test
Influenza C/Taylor/1233/47	1.50E+04 $TCID_{50}$/test
Measles (Edmonston)	3.00E+04 $TCID_{50}$/test
Mumps (Enders)*	3.00E+03 $TCID_{50}$/test

Organism/Virus	Test Concentration**
Parainfluenza virus 1	3.00E+04 $TCID_{50}$/test
Parainfluenza virus 2	1.10E+05 $TCID_{50}$/test
Parainfluenza virus 3	6.80E+05 $TCID_{50}$/test
Parainfluenza virus 4A	3.00E+04 $TCID_{50}$/test
Rhinovirus Type 2	3.00E+03 $TCID_{50}$/test
Rhinovirus Type 15	3.00E+04 $TCID_{50}$/test

cfu/test = colony forming units/test TCID50/test = 50% tissue culture infectious dose

*This organism/virus may interfere with this assay.

**The levels of bacteria were determined by limiting dilution, bacterial culture, and colony counting to give cfu/test. Virus concentrations were determined by standard virology methods, Reed-Muench.

Interfering Substances

Several over-the-counter (OTC) products, whole blood, mucin and blood agar were evaluated with the Sofia Strep A+ FIA at the levels tested (Table 8).

Table 8
Interference Testing

Substance	Concentration
Crest Pro-Health Deep Clean Mint Mouth wash (Cetylpyridnium chloride)	24% v/v
Listerine Original Antiseptic Mouth wash (Eucalyptol, Menthol, Methyl salicylate, and Thymol)	24% v/v
Listerine Cool Mint Antiseptic Mouth wash (Eucalyptol, Menthol, Methyl salicylate, and Thymol)	24% v/v
RiteAid Sore throat relief (Benzocaine and Menthol)	24% v/v
Chloraseptic Max Sore Throat (Phenol and Glycerin)	24% v/v
Dimetapp Children's Cold & Cough (Brompheniramine maleate, Dextromethorphan HBr, and Phenylephrine HCl)	24% v/v
RiteAid Children's Cold & Allergy (Brompheniramine maleate and Phenylephrine HCl)	24% v/v
CVS Children's Cold & Cough DM (Brompheniramine maleate, Dextromethorphan HBr, and Phenylephrine HCl)	24% v/v
RiteAid tussin cough&cold mucus relief CF (Dextromethorphan HBr, Guaifenesin, and Phenylephrine HCl)	24% v/v
Robitussin Max Strength Multi-Symptom CF Max (Dextromethorphan HBr, Guaifenesin, and Phenylephrine HCl)	24% v/v
Robitussin Night Time Multi-Symptom Cold CF (Acetaminophen, Diphenhydramine HCl, and Phenylephrine HCl)	24% v/v
Cepacol Sore Throat Cherry (Benzocaine and Menthol)	24% w/v
Halls Triple Soothing Action Cherry (Menthol)	24% w/v
Halls Triple Soothing Action Menthol-lyptus (Menthol)	24% w/v
Ricola Natural Herb Cough Drops (Menthol)	24% w/v
Sucrets Complete Vapor Cherry (Dyclonine Hydrochloride and Menthol)	24% w/v
Chloraseptic Sore Throat Cherry (Phenol and Glycerin)	24% w/v
BreathSavers Spearmint (Cetylpyridnium chloride)	24% w/v

Substance	Concentration
Tic Tac freshmints (Eucalyptol, Menthol, Methyl salicylate, and Thymol)	24% w/v
Cheetos, Flaming Hot	12% w/v
Doritos, Nacho Flavor	12% w/v*
Fresh Whole Blood	75 µL/swab**
Mucin	4.3% w/v***
Sheep Blood Agar (5% Sheep Blood)	24% w/v
Horse Blood Agar (5% Horse Blood)	24% w/v

*Nacho Flavor Doritos interfered at 25% w/v
** Fresh Whole Blood interfered at 100 µL/swab
*** Bovine submaxillary mucin interfered at 28.7 mg/mL

Conclusion:

These studies demonstrated the substantial equivalence of the Sofia Strep A+ FIA with the Sofia to the existing product Sofia Strep A FIA with Sofia (K123793).