April 3, 2020

Sekisui Diagnostics, LLC
Nisha Li
Principal Regulatory Affairs Specialist
6659 Top Gun Street
San Diego, California 92121

Re: K192719
Trade/Device Name: OSOM ULTRA PLUS FLU A&B Test
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test system
Regulatory Class: Class II
Product Code: PSZ
Dated: September 24, 2019
Received: September 26, 2019

Dear Nisha Li:

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,

Steven Gitterman, M.D., Ph.D.
Deputy Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192719

Device Name
The OSOM® ULTRA PLUS FLU A&B Test

Indications for Use *(Describe)*
The OSOM® ULTRA PLUS FLU A&B Test is an in vitro rapid diagnostic immunochromatographic assay intended for the qualitative detection of influenza type A and type B nucleoprotein antigens directly from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection.

It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. This test is not intended for the detection of influenza C viruses.

A negative test result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the US 2018-2019 influenza season when A/H1N1pdm09 and influenza A/H3N2 were the predominant influenza A viruses in circulation, and the influenza B Yamagata and Victoria lineages were in co-circulation. When other influenza A or B viruses are emerging, performance characteristics may vary.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

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

This 510(k) summary is being submitted in accordance with the requirements 21 CFR 807.92.

The assigned 510(k) number is: K192719

1. Sponsor/Applicant Name and Address

Company Name: Sekisui Diagnostics, LLC

Address: 6659 Top Gun Street
San Diego, CA 92121

Telephone: 858-777-2668

Contact Person: Nisha Li, Principal Regulatory Affairs Specialist

Date Summary Prepared: 09/25/2019

2. Device Name and Classification

Trade Name: OSOM® ULTRA PLUS FLU A&B Test

Regulation: 21 CFR 866.3328 – Influenza virus antigen detection test system

Classification of Device: Class II

Product Code: PSZ

Panel: Microbiology (83)

Special Conditions for Use Statement: For prescription use

3. Predicate Device

Quidel Corp QuickVue® Influenza A+B Test (K180288)

4. Device Description

Operating Principle

The OSOM® ULTRA PLUS FLU A&B Test consists of a test stick that separately detects influenza A and B. The test procedure requires the solubilization of the nucleoproteins from a swab by mixing the swab in Extraction Buffer. The test stick is then placed in the sample mixture, which then migrates along the membrane surface. If influenza A and/or B viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by another a rat anti-influenza A and/or mouse anti-influenza B antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the stick for results to be valid. The appearance of a second and possibly a third light pink to purple

line in the test line region indicates an A, B or A and B positive result. A visible control line with no test line is a negative result.

OSOM® ULTRA PLUS FLU A&B Test Kit Contents

OSOM ULTRA PLUS FLU A&B Test Kit contains the following components:

25 - Test Sticks

25 - Sterile Nasal Swabs

25 - Extraction Buffer vials each containing: 0.25 mL phosphate buffered salt solution (with 0.09% sodium azide as a preservative)

1 - Influenza A Positive Control Swab (packaged with a desiccant tablet): coated with non-infectious recombinant influenza A containing 0.05% sodium azide

1 - Influenza B Positive Control Swab (packaged with a desiccant tablet): coated with non-infectious recombinant influenza B containing 0.05% sodium azide

1 - Instructions for Use (IFU)

1 - Quick Reference Guide (QRG)

1 - Workstation

Note: (2 extra Test Sticks and Extraction Buffer vials have been included in the kit for External Quality Control Testing)

5. Indications for Use

The OSOM® ULTRA PLUS FLU A&B Test is an *in vitro* rapid diagnostic immunochromatographic assay intended for the qualitative detection of influenza type A and type B nucleoprotein antigens directly from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection.

It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. This test is not intended for the detection of influenza C viruses.

A negative test result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the US 2018-2019 influenza season when A/H1N1pdm09 and influenza A/H3N2 were the predominant influenza A viruses in circulation, and the influenza B Yamagata and Victoria lineages were in co-circulation. When other influenza A or B viruses are emerging, performance characteristics may vary.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities,

specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

6. Comparison to Predicate Device

The following table provides a comparison of the characteristics of the OSOM® ULTRA PLUS FLU A&B Test to the predicate device, the Quidel® QuickVue Influenza A+B (K180288).

Similarities		
Item	Predicate Device: QuickVue® INFLUENZA A+B Test K180288	Proposed 510(k) Device: OSOM® ULTRA PLUS FLU A&B Test
Indications for Use	The QuickVue® Influenza A+B Test allows for the rapid, qualitative detection of influenza type A and type B antigens directly in nasal swab and nasopharyngeal swab specimens from symptomatic patients. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. The test is intended for professional and laboratory use. Performance characteristics for influenza A were established during the 2017/2018 influenza seasons when influenza A/H3N2 and A/H1N1 pandemic were the predominant influenza A viruses in circulation. When other	The OSOM® ULTRA PLUS FLU A&B Test is an *in vitro* rapid diagnostic immunochromatographic assay intended for the qualitative detection of influenza type A and type B nucleoprotein antigens directly from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections. This test is not intended for the detection of influenza C viruses. A negative test result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza virus infection and should not be used as the sole basis for

Similarities		
Item	Predicate Device: QuickVue® INFLUENZA A+B Test K180288	Proposed 510(k) Device: OSOM® ULTRA PLUS FLU A&B Test
	influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	treatment or other patient management decisions. Performance characteristics for influenza A were established during the US 2018-2019 influenza season when A/H1N1pdm09 and influenza A/H3N2 were the predominant influenza A viruses in circulation, and the influenza B Yamagata and Victoria lineages were in co-circulation. When other influenza A or B viruses are emerging, performance characteristics may vary. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Assay Results	Qualitative	Same

Similarities		
Item	Predicate Device: QuickVue® INFLUENZA A+B Test K180288	Proposed 510(k) Device: OSOM® ULTRA PLUS FLU A&B Test
Assay Targets	Influenza A and B antigens	Same
Test Principle	Immunochromatography	Same
Sample Types	Nasal swab; nasopharyngeal swab	Same
Assay Antibodies	Monoclonal antibodies to influenza A and B nucleoproteins	Same
Read Results	Visual	Same
Time to Result	10 minutes	Same
Intended Users and Use Locations	Clinical laboratory and point of care	Same
Storage Temperature	Room Temperature	Same
Assay Controls	Internal procedural control	Same
Differences		
Item	Predicate Device: QuickVue® INFLUENZA A+B Test K180288	Proposed 510(k) Device: OSOM® ULTRA PLUS FLU A&B Test
External Controls	Test kit contains separate Positive and Negative Control Swabs	Test kit contains Positive Control Swabs where Influenza A+ Control Swab acts as a negative for influenza B antigen and conversely, Influenza B+ Control Swab serves as negative control for influenza A antigen.
Extraction Reagents	Reagent solution (salt solution) added to lyophilized buffer (detergents and reducing agents)	Extraction buffer containing salt solution.

7. Performance Summary

Expected Values

The prevalence of influenza varies year to year typically peaking in the winter months. The rate of positivity in influenza testing is impacted by many factors including specimen collection and handling, test method used, patient age, time of year, geographic location, and local disease prevalence.

The overall positivity rate as determined by the OSOM ULTRA PLUS FLU A&B Test during the 2018-2019 clinical study was 33.0% for influenza A and 1.7% for influenza B. The observed results by age are presented in the tables below.

Influenza A Positives by the OSOM ULTRA PLUS FLU A&B Test per Age Group

Age Group	Number of Specimens	Number of Influenza A Positives	Influenza A Positivity Rate
≤ 5 years of age	362	127	35.1%
6 to 21 years of age	479	211	44.1%
≥ 22 years of age	369	61	16.5%
Total	1210	399	33.0%

Influenza B Positives by the OSOM ULTRA PLUS FLU A&B Test per Age Group

Age Group	Number of Specimens	Number of Influenza B Positives	Influenza B Positivity Rate
≤ 5 years of age	362	5	1.4%
6 to 21 years of age	479	9	1.9%
≥ 22 years of age	369	6	1.6%
Total	1210	20	1.7%

Clinical Performance

A prospective clinical study to establish the performance characteristics of the OSOM ULTRA PLUS FLU A&B Test in detecting influenza A and B antigens in nasal and nasopharyngeal swab specimens was conducted with specimens collected from January 2019 to May 2019 at 21 point-of-care (POC) sites across the United States. Testing was performed at POC sites representative of CLIA waived settings by untrained operators with no laboratory training or experience.

Samples were collected from individuals with influenza-like symptoms who provided informed consent. Two (2) nasal swabs or two (2) nasopharyngeal swabs were collected from the same nostril according to standard collection methods from each subject. One (1) nasal or nasopharyngeal swab was used for immediate testing with the OSOM ULTRA PLUS FLU A&B Test per the test procedure. The other nasal or nasopharyngeal swab of the pair was eluted in 3.0 mL of viral transport media (VTM). The sample eluted in VTM was stored at 2-8ºC until transport was made on ice packs to a central reference laboratory. The samples collected in VTM were tested by the reference method, an FDA-cleared molecular test and another FDA-cleared molecular test for discrepant analysis, within the allowable time frames of specimen collection per the product instructions.

Nasal or nasopharyngeal swab specimens were collected from 1228 subjects enrolled in the prospective clinical study. Of those, 18 swab samples were unevaluable due to eligibility criteria, sample handling issues, or inconclusive testing results, leaving a total of 1210 prospective evaluable samples. The subject age and gender distribution for the 1210 prospective evaluable samples is presented in the table below.

Age and Gender Distribution

Age Group	Female	Male	Total
≤ 5 years	175	187	362
6 to 21 years	261	218	479
22 to 59 years	107	206	313
≥ 60 years	19	37	56
Total	562	648	1210

Due to the atypically low prevalence of influenza B virus in the U.S. during the 2018-2019 influenza season, 1210 prospective samples (20 influenza B positive samples and 1190 influenza B negative samples) were supplemented with 317 banked samples collected from previous influenza seasons, for a total of 1527 samples tested by untrained users at POC sites. Of those, one (1) banked sample was unevaluable due to sample handling issues, leaving a total of 316 evaluable banked samples. The banked samples were masked as subject samples, randomized, and incorporated into the daily workflow at three (3) CLIA waived sites that participated in the prospective clinical study.

A total of 1526 samples (1210 prospective samples and 316 banked samples) were included in the evaluation of the assay performance. For a total of 1526 evaluable tests performed, one (1) was invalid (1/1526) for a 0.07% invalid rate (95%CI: 0.01%-0.37%). The performance of the OSOM ULTRA PLUS FLU A&B Test compared to an FDA-cleared molecular comparator method with prospective samples and banked samples is presented in the tables below.

Influenza A Performance - Nasal and Nasopharyngeal Swab Samples

OSOM ULTRA PLUS FLU A&B Test - Influenza A	Comparator Method		
	Positive	Negative	Total
Positive	362	37 [a]	399
Negative	39 [b]	1088 [c]	1127
Total	401	1125	1526
Sensitivity	90.3% (95% CI: 87.0%-92.8%)		
Specificity	96.7% (95% CI: 95.5%-97.6%)		

[a] Flu A was detected in 23/37 false positive specimens using a second FDA-cleared molecular test
[b] Flu A was not detected in 7/39 false negative specimens using a second FDA-cleared molecular test
[c] All banked samples were negative for influenza A
[Two (2) samples did not yield valid results on the second FDA-cleared molecular test]

Influenza B Performance - Nasal and Nasopharyngeal Swab Samples

OSOM ULTRA PLUS FLU A&B Test - Influenza B	Comparator Method		
	Positive	Negative	Total
Positive	132	11 [a]	143

OSOM ULTRA PLUS FLU A&B Test - Influenza B	Comparator Method		
	Positive	Negative	Total
Negative	18 [b]	1365	1383
Total	150	1376	1526
Sensitivity	88.0% (95% CI: 81.8%-92.3%)		
Specificity	99.2% (95% CI: 98.6%-99.6%)		

[a] Nine (9) of the prospective samples and two (2) of the banked samples were false positive with the OSOM ULTRA PLUS FLU A&B Test. Flu B was detected in 3/11 false positive specimens using a second FDA-cleared molecular test.

[b] Four (4) of the prospective samples and 14 of the banked samples were negative by the OSOM ULTRA PLUS FLU A&B Test. Flu B was not detected in 2/18 false negative specimens using a second FDA-cleared molecular test.

Reproducibility Studies

Reproducibility of the OSOM ULTRA PLUS FLU A&B Test, when in the hands of untrained users, was evaluated in a multicenter study. Testing was performed at three (3) of the CLIA waived sites that participated in the prospective clinical study. This study included samples with analyte levels at and below the limit of detection (LoD) for influenza A and influenza B.

A panel of swabs including true negative (no virus), high negative (just below the LoD), low positive (at or near the LoD) and moderate positive (at or near 2x the LoD) for influenza A and B were coded, randomized, and masked to the operators. Samples were masked as subject samples and were presented to the intended use operators for testing throughout the course of a normal testing day. The study was conducted with two operators per site over five non-consecutive days.

The OSOM ULTRA PLUS FLU A&B Test produces reproducible results when tested by multiple untrained intended users, at multiple sites, over multiple days. The study demonstrated that untrained intended users were able to accurately perform and interpret the OSOM ULTRA PLUS FLU A&B Test at and below the level of the LoD for both influenza A and influenza B. The results are presented in the table below.

Reproducibility Study Results - Percent Agreement with Expected Results

Sample Category	Site 1	Site 2	Site 3	Overall
Influenza A High Negative[1]	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza A Low Positive	96.7% (29/30)	100% (30/30)	100% (30/30)	98.9% (89/90)
Influenza A Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza B High Negative[1]	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza B Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza B Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
True Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

[1] The “Expected Result” for High Negative samples is “not detected”.

Analytical Sensitivity: Limit of Detection

The limit of detection (LoD) for the OSOM ULTRA PLUS FLU A&B Test was established in dilution studies performed with 2 influenza A strains and 2 influenza B strains on two lots of the OSOM ULTRA PLUS FLU A&B Test. The LoD represents the concentration of influenza virus that produces consistently positive results ≥ 95% of the time. The approximate LoD concentrations identified for each strain tested are listed in the table below.

Influenza Type	Viral Strain Tested	LoD
A	Influenza A/Michigan/45/15 (H1N1)	$7.1x10^1$ $TCID_{50}$/mL
A	Influenza A/Singapore/INFIMH-16-0019/2016 (H3N2)	$2.2x10^5$ $CEID_{50}$/mL
B	Influenza B/Colorado/6/2017 (Victoria)	$3.5x10^3$ $TCID_{50}$/mL
B	Influenza B/Phuket/3073/13 (Yamagata)	$1.6x10^2$ $TCID_{50}$/mL

Analytical Reactivity

A total of 28 influenza A, B, and C strains were tested with the OSOM ULTRA PLUS FLU A&B TEST A&B Test, at levels at or near the assay limit of detection (LoD). All influenza A isolates gave the expected influenza A positive and influenza B negative results, and all influenza B isolates gave the expected influenza A negative and influenza B positive results. The influenza strain isolates in the table below are listed at the lowest testing concentrations that gave the expected results. *NOTE: The influenza C strain listed below produced the expected influenza A negative and influenza B negative results and is listed at the highest concentration tested.

Influenza Strain	Concentration	Type	Sub Type	Test Result
A/NY/02/09	$1.23x10^1$ $TCID_{50}$/mL	A	H1N1pdm	Detected
A/Mexico/4108/09	$7.24x10^1$ $TCID_{50}$/mL	A	H1N1pdm	Detected
A/Singapore/63/04	$1.57x10^3$ $TCID_{50}$/mL	A	H1N1	Detected
A/Taiwan/42/06	$1.15x10^3$ $TCID_{50}$/mL	A	H1N1	Detected
A/NY/01/09	$5.24x10^1$ $TCID_{50}$/mL	A	H1N1pdm	Detected
A/Canada/6294/09	$2.08x10^3$ $TCID_{50}$/mL	A	H1N1pdm	Detected
A/New Cal/20/99	$1.77x10^2$ $TCID_{50}$/mL	A	H1N1	Detected
A/Solomon Islands/03/06	$2.45x10^1$ $TCID_{50}$/mL	A	H1N1	Detected
A/NY/03/09	7.06 $TCID_{50}$/mL	A	H1N1pdm	Detected
A/Brisbane/10/07	7.06 $TCID_{50}$/mL	A	H3N2	Detected
A/Victoria/361/11	$2.94x10^1$ $TCID_{50}$/mL	A	H3N2	Detected
A/Perth/16/09	$1.77x10^1$ $TCID_{50}$/mL	A	H3N2	Detected
A/Wisconsin/67/05	$7.06x10^1$ $TCID_{50}$/mL	A	H3N2	Detected
A/Florida/2/2006	$8.25x10^4$ $CEID_{50}$/mL	A	H3N2	Detected
A/Texas/71/2007	$3.25x10^3$ $TCID_{50}$/mL	A	H3N2	Detected
A/Texas/50/2012	$1.41x10^1$ $TCID_{50}$/mL	A	H3N2	Detected
B/Malaysia/2506/04	$3.53x10^1$ $TCID_{50}$/mL	B	Victoria	Detected
B/Florida/02/06	$6.29x10^1$ $TCID_{50}$/mL	B	Victoria	Detected
B/Massachusetts/2/12	$3.53x10^2$ $TCID_{50}$/mL	B	Yamagata	Detected

Influenza Strain	Concentration	Type	Sub Type	Test Result
B/Wisconsin/1/10	$1.70x10^1$ $TCID_{50}$/mL	B	Yamagata	Detected
B/Texas/6/11	$1.81x10^2$ $TCID_{50}$/mL	B	Yamagata	Detected
B/Florida/04/06	$1.05x10^2$ $TCID_{50}$/mL	B	Yamagata	Detected
B/Florida/07/04	$6.14x10^1$ $TCID_{50}$/mL	B	Yamagata	Detected
B/Lee/40	$1.77x10^1$ $TCID_{50}$/mL	B	Victoria	Detected
B/Brisbane/60/2008	$1.41x10^1$ $TCID_{50}$/mL	B	Victoria	Detected
B/Colorado/06/2017	$2.51x10^6$ EID_{50}/mL	B	Victoria	Detected
A/Anhui/1/2013	$1.99x10^7$ EID_{50}/mL	A	A (Avian)	Detected
C/Taylor/1233/1947	$2.10x10^5$ $CEID_{50}$/mL	C	C	Not Detected*

Analytical Specificity: Cross-Reactivity and Microbial Interference

The OSOM ULTRA PLUS FLU A&B Test was evaluated with 41 organisms (bacterial, viral, fungal) and human DNA, listed below. Bacterial isolates were tested at concentrations of approximately 10^6 colony forming units per mL (CFU/mL). *Chlamydia pneumoniae* was tested at a concentration at least 2.0 x 10^2 CFU/mL. *Corynebacterium ulcerans* and *Streptococcus pyogenes* were tested at a concentration of at least 1.0 x 10^3 CFU/mL. Viral isolates were tested at approximately 10^5 copy number per mL(CP/mL) or 10^4 - 10^5 tissue culture infectious dose 50% per mL ($TCID_{50}$/mL). Human genomic DNA was diluted to a level greater than the minimum recommended concentration of 10^4 copies/mL in viral transport media (VTM). No cross-reactivity was observed at the concentrations tested, as all of the microorganisms and human genomic DNA produced negative results.

Bacterial / Fungal Panel

Bordetella pertussis
Candida albicans
Chlamydia pneumoniae
Corynebacterium ulcerans
Escherichia coli
Haemophilus influenzae
Klebsiella pneumoniae
Lactobacillus acidophilus Z048
Legionella pneumophila
Moraxella catarrhalis
avirulent Mycobacterium tuberculosis
Mycoplasma hominis
Mycoplasma pneumoniae
Neisseria meningitides
Neisseria gonorrhoeae
Pseudomonas aeruginosa
Staphylococcus aureus MRSA
Staphylococcus aureus MSSA
Staphylococcus epidermidis MRSE
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus salivarius

Viral Panel / DNA

Adenovirus type 1
Adenovirus type 7A
Coronavirus NL63
Coxsackievirus
Cytomegalovirus (CMV)
Epstein-Barr virus (EBV)
Human herpes virus 6 (HHV6), Z29
Human herpes virus 7 (HHV7), SB strain
Parainfluenza virus 1
Parainfluenza virus 2
Parainfluenza virus 3
Measles virus
Mumps
Metapneumovirus 3 type B1
Metapneumovirus 9 type A1
Rhinovirus type 1A
Enterovirus 68
Respiratory syncytial virus type A2 (RSVA)
Respiratory syncytial virus type B (RSVB)

Interfering Substances

The OSOM ULTRA PLUS FLU A&B TEST was evaluated with potential interferents that may be encountered in respiratory specimens. The substances were tested at the concentrations listed in the table below. No interference was observed with the test for any of the substances at the concentrations listed.

Substance	Potential Interferent	Concentration Tested
Substance Control	Dry swab	N/A
Study Control	Viral transport media (VTM)	N/A
Mucus (Bovine)	Mucin Protein	19 mg/mL
Whole Blood	Whole Blood with EDTA	5% vol/vol
Analgesic	Acetaminophen	0.1 mg/mL
NSAIDs	Aspirin	16.2 mg/mL
	Ibuprofen	40 mg/mL
	Naproxen	55 mg/mL
Nasal Corticosteroids	Dexamethasone	0.5 mg/mL
	Fluticasone	50 mg/mL
	Mometasone furoate	2.5 µg/mL
	Budesonide	25 µg/mL
	Flunisolide	68.8 µg/mL
	Triamcinolone acetonide	5.5 µg/mL
	Beclomethasone	16 µg/mL
Nasal Sprays	Oxymetazoline	0.025% vol/vol
	Phenylephrine	0.5% vol/vol
	Sodium Chloride	0.325% vol/vol
Nasal Gel	Sabadilla	4x
	Galphimia glauca	4x, 12x, 30x
	Histaminum hydrochloricum	12x, 30x, 200x
	Luffa operculata	4x, 12x, 30x,
	Sulphur	12x, 30x, 200x
Antiviral	Oseltamivir	5 mg/mL
Antibacterial	Tobramycin	40.0 µg/mL
Throat Lozenge	Benzocaine	2.5% soln.
Antibiotic Nasal Ointment	Mupirocin	0.15mg/mL
Allergy Medicine	Histamine hydrochloricum	1%

Competitive Interference

The performance of the OSOM ULTRA PLUS FLU A&B TEST was evaluated in the presence of high levels of influenza A and influenza B. Contrived high and low titer influenza A (H1N1 and H3N2) and B positive samples were prepared and applied to swabs. The high titer for influenza A was at a concentration of $7.1x10^3$ $TCID_{50}$/mL for H1N1, and $2.2x10^7$ $CEID_{50}$/mL for H3N2; the high titer for influenza B was set at $1.6x10^4$ $TCID_{50}$/mL. The low titer for influenza A was at a concentration of $1.4x10^2$ $TCID_{50}$/mL for H1N1, and $4.4x10^5$ $CEID_{50}$/mL for H3N2; the low titer for influenza B was set at $3.2x10^2$ $TCID_{50}$/mL. High and low viral concentrations of influenza A and B were mixed and tested. No competitive interference on test performance was observed.

8. Conclusion

The information presented in this Premarket Notification demonstrates that the performance of the OSOM ULTRA PLUS FLU A&B Test is substantially equivalent in intended use, technological characteristics, and performance to the predicate device.