SEP 2 5 2009

B. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K092633

The purpose of this 510(k) submission is to update the package insert to include additional analytical reactivity information of the currently cleared 510(k) OSOM® Influenza A&B Test (510(k) K061508).

1. Sponsor/Applicant Name and Address

Company Name:	Genzyme Corporation
Address:	500 Kendall Street Cambridge, MA 01242
Telephone:	(858) 777-2611
Fax:	(858) 452-3258
Contact Person:	Fil V. Buenviaje Manager, Regulatory Affairs
Date Summary Prepared:	August 20, 2009

2. Device Name and Classification

Trade Name:	OSOM Influenza A&B Test
Classification of Device:	21 CFR 866.3330, Influenza virus serological reagents Product Code: GNX, antigens, CF, influenza Virus A, B, C
Classification Panel:	Microbiology
Classification:	Class I

3. Predicate Device

OSOM® Influenza A&B Test (K061508, cleared June 12, 2006)

4. Device Description

The OSOM Influenza 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 mouse anti-influenza A and/or 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 will appear in the test line region indicating an A, B or A and B positive result.

5. Device Intended Use

The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

6. Comparison to Predicate Device

The OSOM® Influenza A&B Test is the same device as the predicate OSOM Influenza A&B Test, no physical or procedural changes have been made. The OSOM Influenza A&B Test Package Insert has been updated to include additional analytical reactivity information.

The OSOM Influenza A&B Test was tested with the H1N1 Influenza A strain Mexico/4108/2009. Results demonstrate that OSOM Influenza A&B test reacts with a cultured strain of the 2009 H1N1 Influenza A virus (A/Mexico/4108/2009) and is detectable.

Thus, OSOM Influenza A&B Test is substantially equivalent to OSOM Influenza A&B Test for use with nasal swabs, which was cleared by the FDA (K061508) for in vitro diagnostic use.

The Table lists the characteristics of the OSOM® Influenza A&B Test (new Performance Characteristic) and the OSOM® Influenza A&B Test (original Performance Characteristic).

Device Characteristics	New Device OSOM Influenza A&B Test	Predicate Device OSOM Influenza A&B Test
Intended Use	The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.	The OSOM Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.
Sample type	Nasal swab	Nasal swab
Analytical principle	Lateral flow immunochromotographic assay	Lateral flow immunochromotographic assay
Antibody	Mouse monoclonals	Mouse monoclonals
Extraction buffer volume	300 uL	300 uL
Read time	10 minutes	10 minutes
Procedural control	Yes	Yes
Control samples supplied (as prepared swabs)	Positive Influenza A Positive Influenza B (Positive A acts as negative B; Positive B acts as negative A	Positive Influenza A Positive Influenza B (Positive A acts as negative B; Positive B acts as negative A

Analytical Reactivity table – Influenza A strains	Addition to Analytical Reactivity table (predicate device): Mexico/4108/2009 H1N1 7.91E+06 EID_{50}/mL	Analytical Reactivity table:

Influenza A Strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
Beijing/262/95	H1N1	8.25E+07
Brazil/11/78	H1N1	NA
Chile/1/83	H1N1	NA
New Jersey/8/76	H1N1	2.78E+08
Taiwan/1/86	H1N1	3.47E+07
Guizhou/54/89	H3N2	7.54E+07
OMS/5389/88	H3N2	NA
Beijing/32/92	H3N2	3.97E+06
England/427/88	H3N2	4.73E+07
Johannesburg/33/94	H3N2	1.61E+07
Leningrad/360/86	H3N2	2.50E+06
Mississippi/1/85	H3N2	NA
Philippines/2/82	H3N2	9.75E+07
Shangdong/9/93	H3N2	1.67E+08
Shanghai/16/89	H3N2	3.49E+08
Shanghai/24/90	H3N2	NA
Sichuan/2/87	H3N2	NA
Kitakyushyu/159/93	H3N2	3.19E+08
Akita/1/94	H3N2	2.90E+08
Beijing/262/95	H1N1	1.71E+08
Yamagata/32/89	H1N1	7.28E+07
New Caledonia/20/99	H1N1	6.86E+07
Panama/2007/99	H3N2	1.40E+08
Wyoming/03/03	H3N2	7.40E+06
Fujian/411/02	H3N2	6.12E+07

7. Conclusion

The information presented in the premarket notification demonstrates that the OSOM Influenza A&B test reacts with a cultured strain of the 2009 H1N1 Influenza A virus (A/Mexico/4108/2009). Although this test has been shown to detect the 2009 H1N1 virus in culture isolates, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The OSOM Influenza A&B test can distinguish between influenza A and B viruses, but it can not differentiate influenza subtypes.

The information presented in the pre-market notification demonstrates that the OSOM Influenza A&B test is substantially equivalent with the current OSOM Influenza A&B test.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

SEP 25 2009

Fil V. Buenviaje, RAC
Manager, Regulatory Affairs
Genzyme Diagnostics
6659 Top Gun Street
San Diego, CA 92121

Re: k092633
Trade/Device Name: OSOM Influenza A&B Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: August 20, 2009
Received: August 27, 2009

Dear Mr. Buenviaje:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K092633

Device Name: OSOM® Influenza A&B Test

Indications for Use: The OSOM® Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections.

This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092633