K061508

JUN 12 2006

genzyme

SECTION C. 510(K) SUMMARY

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for the OSOM® Influenza A&B Test.

1. Sponsor/Applicant Name and Address:

   Genzyme Corporation
   One Kendall Square
   Cambridge, MA 02139

2. Sponsor Contact Information:

   Fred D. Lasky, Ph.D.
   Director, Regulatory Affairs
   Phone: 617.591.5512
   FAX: 617.768.9592
   Email: fred.lasky@genzyme.com

3. Date of Preparation of 510(k) Summary:

   May 31, 2006

4. Device Trade or Proprietary Name:

   OSOM Influenza A&B Test

5. Legally Marketed Devices to which Equivalence is Being Claimed:

   OSOM Influenza A&B Test (K 051244)

6. Device Description:

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.

Principle of the Device

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.

7. Comparison of Technological Characteristics of Genzyme OSOM Influenza A&B Test with Legally Marketed Device:

The similarities with, and differences between, the OSOM Influenza A&B Test, with revised labeling, and the OSOM Influenza A&B Test (K 051244) device are described in the following table.

Summary of Device Similarities and Differences

	OSOM Influenza A&B Test	OSOM Influenza A&B Test (K051244)
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.	Intended for the qualitative detection of influenza A and influenza B viral antigens from nasal swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. The test is for use in clinical laboratories, health clinics, and physician office laboratories.
Assay Format	Lateral flow immunoassay	Lateral flow immunoassay
Specimen	nasal swabs	nasal swabs
Antibodies (labeled and capture)	Mouse monoclonals	Mouse monoclonals
Conjugate	Colloidal gold	Colloidal gold
Objective Test Line	Pink to purple line	Pink to purple line
Internal Control	Yes – Pink to purple line	Yes – Pink to purple line
Time To Result	10 minutes	10 minutes
Cross-reactivity data	Includes test listing of bacterial and viral entities	Includes test listing of bacterial entities

8. Potential Interfering Substances

The following potential cross-reactant viruses were tested at levels greater than the limits of detection of the OSOM Influenza A&B Test for both influenza A and B (4.4×10^4/test and 1.4×10^5/test, respectively), and were found to have no affect on the performance.

Virus
Adenovirus Type 1
Adenovirus Type 2
Adenovirus Type 3
Adenovirus Type 6
Coxsackievirus B2
Coxsackievirus B3
Coxsackievirus B4
Coxsackievirus B5
Echovirus Type 6
Echovirus Type 11 (Gregory)
Echovirus 30
Measles virus
Mumps virus (Enders strain)
Parainfluenza virus Type 1
Parainfluenza virus Type 3
Parainfluenza virus Type 4B
Rhinovirus 3
Rhinovirus 7
RSV (Long strain)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 12 2006

Fred D. Lasky, Ph.D.
Director of Regulatory Affairs
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142

Re: k061508
Trade/Device Name: OSOM® Influenza A&B Test
Regulation Number: 21CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: May 31, 2006
Received: June 1, 2006

Dear Dr. Lasky:

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 either class II (Special Controls) or class III (PMA), 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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061508

Device Name: OSOM Influenza A&B Test

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061508