510(k) Summary

NOV 3 0 2001

K011684

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-2000

Contact Person: Luann Ochs

Date Prepared: May 29, 2001.

2) Device name

Proprietary name: Roche Diagnostics Influenza A/B Rapid Test

Common name: Influenza virus detection reagents

Classification name: Antigens, CF (including CF control), influenza virus A, B, C

3) Predicate device

We claim substantial equivalence to the previously cleared Roche Diagnostics Influenza A/B Rapid Test (K993048).

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4) Device Description

The Influenza A/B Rapid Test consists of swabs, reaction cups, test strips, and reagent solutions.

The test detects the viral nucleoprotein associated with the viral nucleic acid. The nucleoprotein is released by lysing the virus envelop with the lysis/elution solution. Since the nucleoprotein is type specific only (not subtype specific), the test uses two pairs of monoclonal antibodies – one pair is specific for Influenza A, the other is specific for Influenza B. The antibody pairs are conjugated to either biotin or digoxigenin.

In the presence of the viral antigen, a sandwich complex is formed, consisting of the biotin-conjugated antibody, the nucleoprotein, and the digoxigenin-conjugated antibody. When the test strip is placed in the reaction cup, the complex migrates chromatographically, solubilizing colloidal gold particles incorporated in the red pad of the strip. The colloidal gold particles bind to the digoxigenin of the complex, which is then bound by the biotin to the immobilized streptavidin on the strip (positive result line). Any excess gold particles continue to migrate to the second line (control line), which then becomes visible. This indicates the correct chromatographic migration.

The test reagent formulation has been modified slightly to produce improved specificity, and allow the use of nasal swab samples.

5) Intended use

The Influenza A/B Rapid Test is a qualitative immunoassay for the rapid detection of Influenza A/B viral antigens from throat or nasal swab specimens. This test is intended for professional *in vitro* diagnostic use to aid in the diagnosis of Influenza infections, and to gather epidemiological information for detection of Influenza outbreaks. When used for diagnosis, negative assay results should be confirmed by cell culture. This assay does not detect the presence of Influenza C viral antigens.

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6) Comparison to predicate device

The new, modified Roche Diagnostics Influenza A/B Rapid Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the previously cleared Roche Diagnostics Influenza A/B Rapid Test.

Similarities:

Feature	RDC Influenza A/B Rapid Test	Modifed RDC Influenza A/B Rapid Test
Intended use	Detection of Influenza A and B viral antigen	Detection of Influenza A and B viral antigen
Indication for use	Aid in the diagnosis of influenza A or B viral infections.	Aid in the diagnosis of influenza A or B viral infections.
Test Principle	Direct visualization of antigen-antibody complex binding to a surface.	Direct visualization of antigen-antibody complex binding to a surface.
Results	Positive or negative qualitative results	Positive or negative qualitative results
Quality control	Internal procedural quality control, external quality control solutions	Internal procedural quality control, external quality control solutions

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6) Comparison to predicate device, continued

Differences

Feature	RDC Influenza A/B Rapid Test	Modified RDC Influenza A/B Rapid Test
Sample type	Throat swab	Throat swab, nasal swab
Performance vs. Cell Culture	Sensitivity 68.4% Specificity 80.7%	Throat Swab: Sensitivity 69.7% Specificity 93.3% Nasal Swab: Sensitivity 77.4% Specificity 93.0%

Benefits:
The modified test allows for the use of nasal swabs in addition to throat swabs, and shows improved specificity over the previous version.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 3 0 2001

Ms. Luann Ochs
Director, Regulatory Submissions
Roche Diagnostics Corporation
Near Patient Testing
9115 Hague Road, P.O. Box 50457
Indianapolis, IN 46250-0457

Re: K011684
Trade/Device Name: Roche Diagnostics Influenza A/B Rapid Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: I
Product Code: GNX
Dated: November 16, 2001
Received: November 19, 2001

Dear Ms. Ochs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):
Device Name: Roche Diagnostics Influenza A/B Rapid Test
Indications for Use:

The Influenza A/B Rapid Test is a qualitative immunoassay for the rapid detection of Influenza A/B viral antigens from throat swab or nasal swab specimens. This test is intended for professional *in vitro* diagnostic use to aid in the diagnosis of Influenza infections, and to gather epidemiological information for detection of Influenza outbreaks. When used for diagnosis, negative assay results should be confirmed by cell culture. This assay does not detect the presence of Influenza C viral antigens.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Wordy Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011684

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)