SEP 10 1997

Appendix D
Safety and Effectiveness Summary for ViraZyme® Influenza ID Test for Influenza Types A and B Virus

This information is provided as a summary of the safety and effectiveness of the ZymeTx, ViraZyme® Influenza ID Test for Influenza Types A and B Viruses. For more detailed information please refer to the product package insert.

The ViraZyme® Influenza ID Test for Influenza Types A and B Viruses is an endogenous viral-encoded enzyme assay (EVEA) and is intended for use in the qualitative determination of influenza types A and B from throat swab specimens. The ViraZyme® Influenza ID Test is not intended for the detection of influenza C.

Influenza types A and B virus possess surface glycoproteins with neuraminidase activity, that hydrolyze substrates which contain alpha-ketosidically linked N-acetylneuraminic acid (Neu5Ac). A modified Neu5Ac molecule has been synthesized and coupled to a chromogen to produce the neuraminidase substrate. In the presence of influenza types A and B virus the chromogenic substrate is then cleaved by the action of viral neuraminidase, releasing a free chromogen. This free chromogen precipitates to produce a blue color. The blue precipitate is then concentrated and collected from the reaction mixture onto a filter device.

PERFORMANCE CHARACTERISTICS

Clinical studies were performed using the ViraZyme® Influenza ID Test for Influenza Types A and B Virus at seven separate locations throughout the United States. A portion of these sites conducted studies comparing the ViraZyme® Influenza ID Test results to results obtained from standard culture confirmation with monoclonal antibodies. All seven of the sites conducted reproducibility studies to determine that the ViraZyme® Influenza ID Test would perform similarly in various physician offices, laboratories, clinics and hospital settings.

A total of 157 throat swab specimens were collected from field sites during the 1995-96 influenza season between November 11, 1995 to March 29, 1996. Each of these specimens were tested by the ViraZyme® Influenza ID Test and tested by the reference method of viral isolation and culture confirmation with monoclonal antibodies. Six physicians and their nurses and technicians, from two separate physician offices in a Southwest region participated in the collection and testing of ViraZyme® Test. Duplicate throat swab specimens were collected and transported by courier to a Southwestern viral testing laboratory for the culture portion of this testing.

Of the 157 specimens collected and tested, a total of 49/157 were positive by the viral isolation and culture confirmation method for **influenza A** (31%); 33/157 were positive by the viral isolation and culture confirmation method for **influenza B** (21%); 1/157 were positive by the viral isolation and culture confirmation method for **parainfluenza type 1** (1%); 1/157 were positive by the viral isolation and culture confirmation method for **adenovirus** (1%); and 73/157 were negative by the viral isolation and culture confirmation method for the respiratory viruses (46%). No parainfluenza type 2 or 3, or respiratory syncytial virus were detected by the viral isolation and culture confirmation method during this study.

SENSITIVITY AND SPECIFICITY RESULTS

Detection of Influenza Types A and B

The ViraZyme® Influenza ID Test detected 51/82 (62.2%) of culture confirmed positives for influenza type A and type B from throat swab specimens. The ViraZyme® Influenza ID Test properly identified 74/75 (98.7%) of culture confirmed negatives for influenza types A and B virus from throat swab specimens.

Detection of Influenza Types A

The ViraZyme® Influenza ID Test detected 32/49 (65.3%) of culture confirmed positives for influenza type A and type B from throat swab specimens. The ViraZyme® Influenza ID Test properly identified 107/108 (99.1%) of culture confirmed negatives for influenza type A virus from throat swab specimens.

Detection of Influenza Types B

The ViraZyme® Influenza ID Test detected 19/33 (57.6%) of culture confirmed positives for influenza type B from throat swab specimens. The ViraZyme® Influenza ID Test properly identified 123/124 (99.2%) of culture confirmed negatives for influenza type B virus from throat swab specimens.

VIRAZYME® INFLUENZA ID TEST RESPRODUCIBILITY

There was 100% correlation of results during the reproducibility testing of the ViraZyme® Influenza ID Test at seven physician offices, clinics, research laboratories and hospital settings conducted during the 1996-97 influenza season. We believe that this adequately demonstrates that the ViraZyme® Influenza ID Test will perform similarly in various test environment settings in the hands of various personnel.

TECHNICAL INFORMATION

For technical information and comments regarding this product, you may contact the ViraZyme® Influenza ID Product Manager at (405) 271-1314.

This Safety and Effectiveness Summary has been provided as a part of the 510(k) notification for the ViraZyme® Influenza ID Test for Influenza Types A and B Virus

Craig D. Shimasaki, Ph.D

Craig D. Shimasaki, Ph.D.
Vice President of Research

4/23/97

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Craig D. Shimasaki, Ph.D.
ZymeTx, Inc.
800 Research Parkway
Suite 100
Oklahoma City, OK 73104

SEP 10 1997

Re: K971494
Trade Name: VstatFlu™ Test for Influenza Types A and B Virus
Regulatory Class: I
Product Code: GNX
Dated: July 18, 1997
Received: July 21, 1997

Dear Dr. Shimasaki:

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 (for the indications for use stated in the enclosure) 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

Page: 1 of 1

510(k) Number (if known): K971494

Device Name: ZstatFlu™ Test for Influenza Types A and B Viruses

Indications for use:

The ViraZyme® Influenza ID test is a direct specimen test indicated for use in the qualitative detection of both influenza types A and B virus from throat swab specimens. The ViraZyme® Influenza ID test may be used when a patient is suspected of having symptoms of an influenza-like illness. These symptoms can include, but are not limited to the following: fever of 38.5°C, sore throat, headache, myalgia, rhinitis, vomiting, chills, malaise, and cough. A positive ViraZyme® result would indicate the presence of influenza type A or B virus. A negative result is considered presumptive and should be confirmed by culture. The ViraZyme® Influenza ID test does not detect influenza C, and is indicated for *in Vitro* Diagnostic Use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over-The-Counter Use:** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971494