3/4/98

K984596

H. 510(k) SUMMARY, 807.87(h)

510(k) SUMMARY

Submitters Name:	ZymeTx, Inc.
Address:	800 Research Parkway, Suite 100 Oklahoma City, OK 73104
Telephone Number:	(405) 271-1314
Facsimile Number:	(405) 271-1944
Contact Person:	Craig D. Shimasaki, Ph.D.
Device Name Trade/Proprietary:	ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies
Common Name:	Fluorescently-labeled monoclonal antibodies for the detection of influenza A and B viruses
Classification Name:	Influenza virus serological reagents have been designated Class I (general controls) by the Microbiology Device Classification Panel, Part 866, Subpart D and 8663.3330 of 21 CFR.
Equivalent Device(s):	The anti-influenza A and B monoclonal antibodies in the ViraSTAT® FITC-Labeled Anti-Influenza A and B test panel are substantially equivalent to other monoclonal antibodies for detection of influenza A and B such as Bartels' Viral Respiratory Screening and Identification Kit and in Dako's Imagen Influenza A and B Kit which are FDA marketing-cleared and were used as the reference antibodies for the clinical trials.
Device Description:	The ViraSTAT® FITC-Labeled Anti-Influenza A and B monoclonal antibodies are fluorescently-labeled antibodies for use in culture confirmation of influenza A and B infections, respectively, in standard cell culture. The virus to be detected is grown in the appropriate cell culture system, fixed on a slide or coverslip and then the cell preparation is stained with the fluorescently-labeled monoclonal antibody. The stained sample is then viewed under a fluorescent microscope for a positive or negative identification. A positive sample is determined when cells displaying typical apple-green fluorescence are observed. Fluorescence may be present in the nucleus alone, in the nucleus and the cytoplasm, or in the cytoplasm alone. A negative sample is determined when slide wells or coverslips show no specific apple-green fluorescence in the cells and have at least 50 intact red counterstaining cells per well or 50% of the monolayer remaining on the coverslips or slides that are counterstained red.
Intended Use:	The ViraSTAT® FITC-Labeled Anti-Influenza A and B monoclonal antibodies test panel is intended for the detection of influenza A and B virus in infected cell cultures through the use of the ViraSTAT® FITC-Labeled Anti-Influenza Pool and the identification of influenza A and B by typing with separate ViraSTAT® FITC-Labeled Anti-Influenza type A and B, monoclonal antibodies, respectively.

Tech. Characteristics: The monoclonal antibodies contained in the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies test panel are similar to other available FDA marketing-cleared fluorescently-labeled available antibodies. The basis for these tests is the reaction between antigens found on these viruses and the monoclonal antibody specific to the virus type. Like other available antibodies, the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies are developed for use as a direct immunofluorescence assay (DFA) since the ViraSTAT® test panel reagents have the FITC directly attached to the determining antibody. The ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies are also manufactured in a liquid state as are other similar antibodies. We believe that the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies test panel is substantially equivalent to standard cell culture confirmation of influenza virus infection by fluorescently-labeled antibodies.

Performance Data: Clinical trial evaluations involved testing with the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies compared to testing with commercially available 510(k) marketing-cleared monoclonal antibodies. A total of 962 culture isolates from respiratory specimens were tested at four test sites. The majority of these, 944 were culture isolates from fresh throat swab specimens and the rest were from frozen isolates. Of the 962 specimen isolates tested, 363 were identified as influenza A and 99 were identified as influenza B with the reference antibodies. The other 500 tested as influenza-negative with the reference antibodies. There was 100% correlation of specificity and sensitivity results with the reference monoclonal antibodies and the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies for all clinical trial specimens. All specimens identified as influenza A with the reference antibodies were appropriately positive for influenza A with the ViraSTAT®MAbs. Likewise, all specimens identified as influenza B with the reference antibodies were appropriately positive for influenza B with the ViraSTAT® MAbs. Results showed there was no cross reactivity between the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies All specimens testing negative for influenza with the reference antibodies were also negative with the ViraSTAT® MAbs. In addition, testing of cultures of other (non-influenza) viruses with the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies gave negative results with ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies confirming the specificity for influenza.

Conclusions: Performance of the ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies was shown to be equivalent to that for the reference anti-influenza A and B monoclonal antibodies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 4 1999

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

Re: K984596
Trade Name: ViraSTAT® FITC-Labeled Anti-Influenza A and B Monoclonal Antibodies
Regulatory Class: I
Product Code: GNR
Dated: December 23, 1998
Received: December 28, 1998

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 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). 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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

Indications for Use Statement

510(k) Number (if known): ~~K984500~~ K984596

Device Name: **ZymeTx, Inc. ViraSTAT® FITC-Labeled Anti-Influenza Types A and B Monoclonal Antibodies**

Indications For Use: The ViraSTAT® FITC-Labeled Anti-Influenza test panel is intended for the qualitative detection and confirmation of influenza A and B virus isolates from infected cell cultures through the use of the ViraSTAT® FITC-Labeled Anti-Influenza Pool and the identification and confirmation of influenza A and B by typing with separate ViraSTAT® FITC-Labeled Anti-Influenza type A or B, monoclonal antibodies, respectively. Performance characteristics have not been established for direct specimen staining.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984596

Prescription Use ✘ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)