JUL - 1 1997

Class III Summary

Type of Problems:

1. Loss of biological activity caused by antigenic deterioration.

2. Loss (Removal) of the fixed cells in either the infected or uninfected slide wells.

HSV-1 Antigen Control slides are to be used by laboratories to determine the activity of staining reagents. If the HSV-1 Antigen Control Slides had deteriorated to a point of non-reactivity or the cells had dislodged and were subsequently used by a laboratory, the indication would be that the staining reagents were not working properly. This would cause the test to be discarded but would not lead to a false positive or false negative clinical test result.

ral
ntigens
Inc. 5171 Wilfong Road, Memphis, Tennessee 38134-5611 Phone (901) 382-8716
FAX (901) 382-0027

Date 3-10-97

Class III Certification

510(k) Reference Number - **K964874**

Device name: HSV-1 Antigen Control Slides

I certify, that in my capacity as Vice President of Regulatory Affairs, of Viral Antigens, Inc. that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for HSV-1 Antigen Control Slides. I further certify that I am aware of the types of problems to which HSV-1 Antigen Control Slides is susceptible and that, to the best of my knowledge , the following summary of the types and causes of safety or effectiveness problems about HSV-1 Antigen Control Slides is complete and accurate.

Terry S. Ratcliffe
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Terry S. Ratcliffe
Vice President Regulatory Affairs
Viral Antigens, Inc.
5171 Wilfong Road
Memphis, TN 38134

JUL - 1 1997

Re: K964874
Trade Name: HSV-1 Antigen Control Slides
Regulatory Class: III
Product Code: GQN
Dated: January 14, 1997
Received: January 15, 1997

Dear Mr. Ratcliffe:

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 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.

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

510(k) Reference Number - **K964874**

Device name: HSV-1 Antigen Control Slides

INDICATIONS FOR USE:

In order to confirm HSV-1 infections physicians frequently use tissue culture techniques. This involves obtaining patient samples, inoculation of these samples into established cell lines (Such as MRC-5 cells) and monitoring these cells for HSV-1 induced cytopathology. Frequently the cells inoculated with patient sample are then stained as an aid in the diagnosis of HSV-1 infections.

HSV-1 Antigen Control Slides are quality control materials used to confirm the accuracy of staining reagents used in cell culture confirmatory assays for the detection of HSV-1. Each individual slide contains two wells of fixed cells, one HSV-1 infected well and one uninfected well. The two wells of cells on the **HSV-1 Antigen Control Slide** are stained concomitantly with the cells inoculated with patient sample providing both a positive and negative control for the staining reagents and procedure. Lack of staining of the positive well indicates a failure of one or more components of the staining reagent.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K964874

Prescription Use ✓
(Per 21 CFR 801.109)