



Zeus Scientific, Inc.  
c/o Ewa K. Nadolczak  
Manager, Clinical Affairs  
200 Evans Way  
Branchburg, NJ 08876

MAY 20 2011

Re: k103603

Trade/Device Name: Zeus ELISA HSV gG-2 IgG Test System  
Regulation Number: 21 CFR 866.3305  
Regulation Name: Herpes simplex virus serological assays  
Regulatory Class: Class II  
Product Code: MYF  
Dated: April 13, 2011  
Received: April 14, 2011

Dear Ms. Nadolczak:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

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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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 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: K103603

Device Name: ZEUS ELISA HSV gG-2 IgG Test System

Indications for Use:

The ZEUS ELISA HSV gG-2 IgG Test System is intended for the qualitative detection of type specific IgG class antibodies to Herpes Simplex Virus Type 2 (HSV-2) in human serum. The test is intended for testing sexually active individuals or pregnant women for aiding in the presumptive diagnosis of HSV-2 infection.

The predictive value of positive or negative results depends on the population's prevalence and the pretest likelihood of HSV-2. The test is not intended for donor screening or for self testing.

The performance of this assay has not been established for use in a pediatric population, neonates, or immunocompromised patients.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

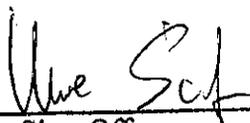
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

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