



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Kathryn Kohl
Managing Director
Operations, Scientific & Regulatory
EUROIMMUN US LLC
429 Rockaway Valley Road, Unit 1200
Boonton Township, New Jersey 07005

JUN 28 2007

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k061239

Trade/Device Name: EUROIMMUN Anti-HSV-1 ELISA (IgG) Kit
EUROIMMUN Anti-HSV-2 ELISA (IgG) Kit
Regulation Number: 21CFR 866. 3305
Regulation Name: Herpes Simplex Virus Serological Reagents
Regulatory Class: Class II
Product Code: MXJ and MYF
Dated: April 28, 2006
Received: May 3, 2006

Dear Ms. Kohl:

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 either class II (Special Controls) or class III (PMA), 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter 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

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predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat". The signature is fluid and cursive, with the first name "Sally" being the most prominent part.

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



ATTACHMENT 1

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061239

Device Name: Anti-HSV-1 ELISA (IgG)

Indications For Use:

The EUROIMMUN Anti-HSV-1 ELISA (IgG) is intended for the qualitative determination of IgG class antibodies against Herpes simplex virus type 1 (HSV-1) specific glycoprotein C1 in human serum. It is intended for the presumptive diagnosis of type specific HSV-1 infection in conjunction with EUROIMMUN Anti-HSV-2 ELISA (IgG) in persons suspected of herpes viral infection.

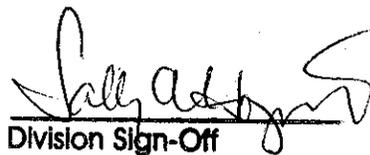
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K061239



INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061239

Device Name: Anti-HSV-2 ELISA (IgG)

Indications For Use:

The EUROIMMUN Anti-HSV-2 ELISA (IgG) is intended for the qualitative determination of IgG class antibodies against herpes simplex virus type 2 (HSV-2) specific glycoprotein G2 in human serum. It is intended for the presumptive diagnosis of type specific HSV-2 infection in conjunction with EUROIMMUN Anti-HSV-1 ELISA (IgG) in persons suspected of herpes viral infection.

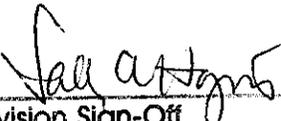
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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