



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 19, 2016

EUROIMMUN US INC.
c/o MR. MICHAEL LOCKE
DIRECTOR OF REGULATORY AFFAIRS
1100 THE AMERICAN ROAD
MORRIS PLAINS, NJ 07950

Re: K141827

Trade/Device Name: EUROIMMUN IFA 40: HEp-20-10 EUROPattern
EUROPattern Microscope and Software

Regulation Number: 21 CFR 866.5100

Regulation Name: Antinuclear antibody immunological test system

Regulatory Class: II

Product Code: DHN, PIV

Dated: March 17, 2015

Received: March 18, 2015

Dear Mr. Locke:

This letter corrects our substantially equivalent letter of April 17, 2015.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT (ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
(OIR)
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141827

Device Name

EUROIMMUN IFA 40: HEp-20-10 EUROPattern & EUROPattern Microscope & Software

Indications for Use (Describe)

Instrument:

The EUROPattern Microscope and Software is an automated system consisting of fluorescent microscope and software that acquires, interprets, stores and displays digital images of stained indirect immunofluorescence slides. The EUROPattern Microscope and Software can only be used with cleared or approved EUROIMMUN in vitro diagnostic assays that are indicated for use on the device. All suggested results obtained with the EUROPattern Microscope and Software must be confirmed by trained personnel.

Assay:

The EUROIMMUN IFA 40: HEp-20-10 EUROPattern is an indirect immunofluorescence antibody test for the qualitative or semi-quantitative determination of IgG antibodies against anti-nuclear antibody (ANA) in human serum with the EUROPattern Microscope and Software automated instrument. This in vitro diagnostic assay is used as an aid in the diagnosis of systemic rheumatic diseases in conjunction with other laboratory and clinical findings. All suggested results obtained with the EUROPattern system must be confirmed by trained personnel.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”