May 24, 2018

EUROIMMUN US, Inc.
Michael Locke
Director of Regulatory Affairs & Quality Management
1 Bloomfield Avenue
Mountain Lakes, New Jersey 07046

Re: K172582
Trade/Device Name: EUROIMMUN IFA Granulocyte Mosaic EUROPattern
EUROIMMUN EUROPLUS Granulocyte Mosaic EUROPattern
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MOB, MVJ, PIV
Dated: August 28, 2017
Received: August 28, 2017

Dear Michael Locke:

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 Part

801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kelly Oliner -S

For
Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172582

Device Name
EUROIMMUN IFA Granulocyte Mosaic™ EUROPattern &
EUROIMMUN EUROPLUS Granulocyte Mosaic™ EUROPattern

Indications for Use *(Describe)*

The EUROIMMUN IFA Granulocyte Mosaic EUROPattern is intended as an indirect immunofluorescence test for the qualitative or semi-quantitative determination of immunoglobulin class IgG anti-neutrophil cytoplasmic antibodies (ANCA) in human serum. It is used as an aid in the diagnosis of ANCA associated vasculitides, in conjunction with other laboratory and clinical findings. The EUROIMMUN IFA Granulocyte Mosaic EUROPattern test kit is intended for use with the EUROPattern microscope and software system. All suggested results obtained with the EUROPattern system must be confirmed by trained personnel.

The EUROIMMUN EUROPLUS Granulocyte Mosaic EUROPattern is intended as an indirect immunofluorescence test for the qualitative or semi-quantitative determination of immunoglobulin class IgG anti-neutrophil cytoplasmic antibodies (ANCA) and the qualitative determination of IgG anti-PR3, anti-MPO, and, if included, anti-GBM antibodies in human serum. It is used as an aid in the diagnosis of ANCA associated vasculitides, in conjunction with other laboratory and clinical findings. The EUROIMMUN EUROPLUS Granulocyte Mosaic EUROPattern test kit is intended for use with the EUROPattern microscope and software system. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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