DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2006

EUROIMMUN US, LLC
c/o Ms. Kathryn Kohl
Managing Director
Tek Campus of Morris County
429 Rockaway Valley Rd. U1200
Boonton TWP, NJ 07005

Re: k060700
Trade/Device Name: EUROIMMUN anti-Proteinase 3 (PR3) ELISA IgG and EUROIMMUN anti-Myeloperoxidase (MPO) ELISA IgG
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: Class II
Product Code: MOB
Dated: March 10, 2006
Received: March 15, 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 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); 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.

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 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), please contact the Office of Compliance at (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Maria Chan for
Dr Robert Becker

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 1

PR3:

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k060700

Device Name: Anti-Proteinase 3 (PR3) ELISA IgG

Indications For Use:

This test kit is designed for the determination of anti-proteinase 3 antibodies (PR3) in human serum and plasma. This test is used as an aid in the differential diagnosis of Wegener's granulomatosis and other autoimmune vasculitides, in conjunction with other laboratory and clinical findings.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K060700

MPO:

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): k060700

Device Name: Anti-Myeloperoxidase (MPO) ELISA IgG

Indications For Use:

This test kit is designed for the determination of anti-myeloperoxidase antibodies (MPO) in human serum and plasma. This test is used as an aid in the differential diagnosis of microscopic polyangitis, Churg-Strauss syndrome and other autoimmune vasculitides, in conjunction with other laboratory and clinical findings.

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) K060700