



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Euro-Diagnostica AB
c/o Mr. Karl A. Posselt
FDA Regulatory Consulting Services
155 Cider Mill Road
Ringoos, New Jersey 08551

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 29 1997

Re: K971690
Trade Name: Immunoscan PR3-ANCA
Regulatory Class: II
Product Code: MOB
Dated: September 2, 1997
Received: September 4, 1997

Dear Mr. Posselt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

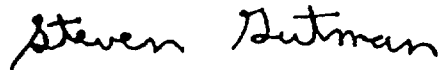
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in dark ink, reading "Steven Gutman". The signature is written in a cursive, slightly slanted style.

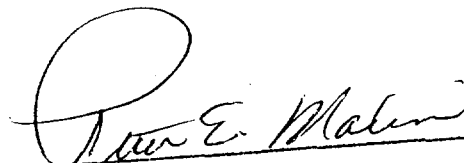
Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971690

8. b). Statement Of Indications For Use**STATEMENT OF INDICATIONS FOR USE**

The Euro-Diagnostica Immunoscan PR3-ANCA Kit is an enzyme immunoassay (EIA) kit for the *in vitro* detection in human serum of the subclass of Anti-Neutrophil Cytoplasmic Antibodies (ANCA) directed against proteinase-3 to be used as an aid in the diagnosis of Wegener's granulomatosis.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971690

Prescription ✓