



SEP - 9 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Dr. Pane Armstrong  
Regulatory Affairs  
Radox Laboratories Limited  
Biochemical Manufacturers  
Ardmore, Diamond Road, Crumlin, Co.  
Antrim, United Kingdom, BT29 4QY

Re: K972220/S1  
Trade Name: Rheumatoid Factor Latex-Enhanced Immuno-  
turbidimetric Test Kit  
Regulatory Class: II  
Product Code: DHR  
Dated: August 11, 1997  
Received: August 13, 1997

Dear Dr. Armstrong:

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.

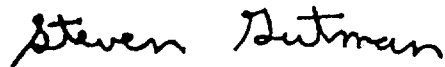
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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,



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

510(k) Number (if known): Not Known

Device Name: Rheumatoid Factor Latex-Enhanced  
Immunoturbidimetric Test Kit

**Indications For Use:**

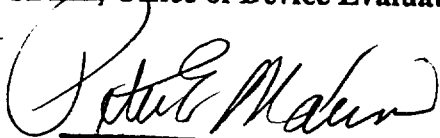
The Randox Rheumatoid Factor Latex-Enhanced Immunoturbidimetric Test Kit is an invitro diagnostic reagent for the quantitative determination of rheumatoid factors (RF) in human serum. This test kit may be used to facilitate the detection and diagnosis of Rheumatoid Arthritis. RF have also been observed in the serum of patients with systemic lupus erythematosus, hepatitis, liver cirrhosis and syphilis. However, in these conditions the RF titre is much lower than in rheumatoid arthritis.

This test kit must be used by suitably qualified personnel under appropriate laboratory conditions.

RF calibrator and RF positive control are for use in the calibration and quality control of RF latex-enhanced immunoturbidimetric assays.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

Prescription Use   
(Per 21 CFR 801.109)

OR

~~Over-The-Counter Use~~

(Optional Format 1-2-96)