



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 3 2000

Ms. Danielle M. Knight
Quality Manager
Cogent Diagnostics Limited
Pentlands Science Park
Bush Loan, Penicuik
Midlothian EH26 OPL
Scotland, UK

Re: K994338
Trade Name: Autostat™ II Rheumatoid Factor IgM ELISA
Regulatory Class: II
Product Code: DHR
Dated: December 16, 1999
Received: December 23, 1999

Dear Ms. Knight:

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 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). 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.

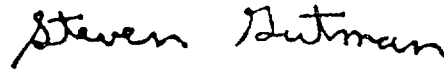
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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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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" (21CFR 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "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

510(k) Number (if known): K 994338Device Name: AUTO STAT II RHEUMATOIDFACTOR IgM ELISA**Indications For Use:**

ENZYME LINKED IMMUNOSORBENT ASSAY METHOD FOR THE SEMI-QUANTITATIVE DETERMINATION OF SPECIFIC IgM RHEUMATOID FACTOR (RF) ANTIBODIES IN HUMAN SERUM.

USES: THE RESULTS OF THE RF IgM ASSAY CAN BE USED AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) WHEN SUPPORTED BY OTHER LABORATORY AND CLINICAL INVESTIGATIONS.

LEVELS OF THESE AUTOANTIBODIES ARE ONE INDICATOR IN A MULTIFACTORIAL DIAGNOSTIC REGIME. THE ASSAY MAY BE USED ON THE HYCOR HYOTEC AUTOMATED EIA INSTRUMENT. FOR IN VITRO DIAGNOSTIC USE ONLY.

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

Concurrence of CDRI, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Clinical Laboratory Devices
510(k) Number K994338

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)