



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

John W. Nelson
Manager, Regulatory Affairs
Bio-Rad Laboratories
4000 Alfred Nobel Drive
Hercules, California 94547-1803

JUL 30 1997

Re: K972024
Coda™ Automated EIA Analyzer
Regulatory Class: I
Product Code: JJI
Dated: May 30, 1997
Received: June 2, 1997

Dear Mr. Nelson:

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 (Pre-market 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 pre-market 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.

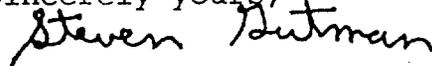
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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

R 970024

JUL 30 1997

APPENDIX B
SUMMARY OF SAFETY AND EFFECTIVENESS



**Bio-Rad
Laboratories**

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SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Bio-Rad Laboratories, Inc.
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Hercules, California 94547
Phone 1-510-741-6015
FAX 1-510-741-5824

Contact Person: John W. Nelson
Manager, Regulatory Affairs

Date Prepared: May 30, 1997

Product Trade Name: Bio-Rad Coda™ Automated EIA Analyzer

Common Name: Coda

Classification Name: Enzyme Analyzer, for Clinical Use, 75JJJ

Predicate Devices

1. Radius™ Immunoassay System,
Bio-Rad Laboratories, K930898.
2. ACS 180 Automated Chemiluminescence
System, Ciba Corning, K902336.
3. Abbott IMX2 Analyzer, Abbott
Laboratories, K931970.

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness of the Bio-Rad Coda Automated EIA Analyzer, the Bio-Rad Coda Automated EIA Analyzer has been compared to the Bio-Rad Radius Immunoassay System K930898. A review of the intended use of each system shows them to be essentially the same in that they are capable of measuring a number of analytes based on the Enzyme Immunoassay (EIA) principle. The intended use of the Bio-Rad Coda Automated EIA Analyzer is stated as: *CODA is an integrated immunoassay analyzer intended for the automation of microplate based assays for in vitro diagnostic use. The system is open, such that a variety of microplate-based enzyme immunoassays (EIA's) can be programmed and run on the instrument. The sample and reagent pipettes, incubator, washer, reader and robotics are housed in the compact benchtop unit. CODA Operation and Data Management software operates in the Windows 95 environment utilizing icon-based commands for operator ease of use.* The intended use of the Bio-Rad Radius Immunoassay System is stated as: *Radius is a fully automated immunoassay system utilizing ELISA based assays for in vitro diagnostic use.*

The Bio-Rad Coda Automated EIA Analyzer (Coda) is a compact, integrated immunoassay system designed for the automation of microplate based (8 wells by 12 strips) chemistries. The sampler, plate-shaker, incubator, washer, reader and robotics are housed in a single compact Main Unit. An external computer handles the operation and data management using software contained on a CD-ROM which operates in the Windows 95 environment.

Enzyme immunoassay (EIA) typically involves the addition of a defined volume of sample to a series of plastic microtitre wells which have been pre-coated with antigen or antibody. The wells are sometimes washed to remove unbound ligand before addition of enzyme conjugate to each well. After incubation, substrate is added followed by a second incubation. The enzyme reaction is "stopped" and the colored reactant product is measured by absorbance at a defined wavelength. The absorbance values of the unknowns are compared to absorbance of calibrators to determine the concentration of the ligand in the sample. The Coda provides an integrated, automated approach to carrying out the above steps all under control of the computer and associated software. All the steps may be programmed into a complete protocol or individual steps may be performed in a manual mode. The Coda is therefore virtually usable with any assay kit using microtitre plates. Output from the spectrophotometer is measured by the computer. Calculation, curve-fitting, result interpretation and other aspects of data management and analysis are automatically performed by the software algorithms.

Bio-Rad RADIUS Immunoassay System (RADIUS) is a fully automated immunoassay system designed for high-capacity which, like the Coda, is based on EIA. All assay operations, including pipetting, diluting and incubating samples and reagents are performed by the RADIUS. Based on a "worklist" the RADIUS determines the quantities and types of reagents and microwell "strips" that will be needed for the run. The RADIUS can do multiple assays on the same sample. All reagents required by the RADIUS are supplied by Bio-Rad Laboratories in RADIUS compatible "troughs". Calculation, curve-fitting, result interpretation and other aspects of data management and analysis are automatically performed by the software algorithms.

The performance of the Bio-Rad Coda Automated EIA Analyzer was evaluated for precision, sensitivity, carry over, and accuracy. The precision studies were done according to NCCLS Evaluation protocol, Vol. 12, No 4, EP5-T2, Appendix C, pp 31-39. Twenty samples each of low, mid-range and high control plus a Bio-Rad anemia control (AN) were analyzed. The Within-Run % CV for the low control was 8.6 and for the mid-range control 7.1. The high control was consistently greater than 25 $\mu\text{IU/mL}$. The %CV for the anemia control was 9.5. Total precision for the low control was 9.6% and for the mid-range control 7.7%. Again the high control was consistently greater than 25 $\mu\text{IU/mL}$. The total precision for the anemia control was 14.0%. The measuring range (sensitivity) determined that the lowest level of TSH that could be distinguished from the zero standard is 0.034 $\mu\text{IU/mL}$ at the 95% confidence limit on the Coda.

The correlation study, to determine accuracy, of Bio-Rad Coda Automated EIA Analyzer compared to the Bio-Rad RADIUS Immunoassay System followed NCCLS Document EP9-T. For 111 samples, the correlation coefficient, "r", was 0.995.

When comparing the Bio-Rad Coda Automated EIA Analyzer to the predicate, it can be concluded from the correlation study and similarities of the general characteristics of the two systems (Appendix C), that the Bio-Rad Coda Automated EIA Analyzer and the Bio-Rad RADIUS Immunoassay System are substantially equivalent. Based on the establishment of substantial equivalence, the safety and effectiveness of the Bio-Rad Coda Automated EIA Analyzer is confirmed.

