APR - 2 1998

K980521

SUMMARY OF SAFETY AND EFFECTIVENESS

Technicon RA™ and opeRA Chemistry Systems
Digoxin (Procedure Using Syva Emit 2000® Reagents)

Listed below is a comparison of the performance between the Technicon RA/opeRA Digoxin method and a similar device that was granted clearance of substantial equivalence (Bayer Immuno 1 Digoxin method). The information used in the Summary of Safety and Effectiveness was extracted from the RA/opeRA Digoxin method sheet and the Immuno 1 Digoxin method sheet.

INTENDED USE

This in vitro diagnostic procedure is intended to quantitatively measure the concentration of digoxin in human serum and plasma on the Technicon RA/opeRA systems. Measurements obtained with this procedure are used to monitor circulating levels of this drug so that proper therapeutic level is maintained while avoiding toxicity.

METHOD		RA/opeRA	Immuno 1
Part No.	Reagents	T-4H019	T01-2875-51
	Calibrators	T-4H209	T03-2864-01
Minimum Det. Conc.		0.20 ng/mL	0.04 ng/mL
Precision (Total)		20.0% @ 0.4ng/mL 9.0% @ 1.3ng/mL 9.0% @ 2.8ng/mL	8.2% @ 0.7ng/mL 4.2% @ 2.2ng/mL 3.6% @ 3.4ng/mL
Correlation		y=1.08x+0.11 where y=RA/opeRA x=Immuno 1 n=39 r=0.949 Syx=0.2 ng/mL Range of RA analyte concentration = 0.2 - 2.8 ng/ml	

Gabriel J. Muraca, Jr.

3/20/98

Date

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation, BG-DS
511 Benedict Ave.
Tarrytown, NY. 10591-5097
Tele. 914-524-3494

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 2 1998

Gabriel Muraca, Jr.
Manager of Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K980521
Syva Emit® 2000 Digoxin Assay and Calibrator for the Technicon RA®/opeRA™ Systems
Regulatory Class: II
Product Code: KXT
Dated: March 10, 1998
Received: March 12, 1998

Dear Mr. Muraca:

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 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.

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 Gutman

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): K980521

Device Name: **Technicaon RA® and opeRA Chemistry Systems**
Digoxin (Procedure Using Syva Emit 2000* Reagents)

Indications For Use:

This *in vitro* diagnostic procedure is intended to measure the concentration of digoxin in human serum or plasma on a Technicon RA-500®, Technicon RA-1000®, Technicon RA-XT™, Technicon RA-2000®, or opeRA system. Measurements obtained with this procedure are used to monitor circulating levels of this drug so that the proper therapeutic level is maintained while avoiding toxicity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980521