K971713

SUMMARY OF SAFETY AND EFFECTIVENESS

N-Acetylprocainamide Assay for Bayer Immuno 1® System

Listed below is a comparison of the performance between the Immuno 1 N-Acetylprocainamide (NAPA) assay and a similar device that was granted clearance of substantial equivalence (Syva EMIT® N-Acetylprocainamide Assay, Behring Diagnostics Inc.). The information used in the Summary of Safety and Effectiveness was extracted from the Immuno 1 N-Acetylprocainamide Method Sheet and the Syva EMIT® N-Acetylprocainamide Assay Insert Sheet.

INTENDED USED

This *in vitro* method is intended to quantitatively measure n-acetylprocainamide, the pharmacologically active metabolite for procainamide, an antiarrhythmic drug, in human serum or plasma (lithium heparin) using Syva EMIT® N-Acetylprocainamide Assay on a *Bayer Immuno-1®* system. Measurements of n-acetylprocainamide are used in the diagnosis and treatment of procainamide overdose and in monitoring levels of n-acetylprocainamide to ensure appropriate therapy.

METHOD	**Immuno 1 NAPA Assay**	**Syva EMIT® NAPA Assay** (predicate Device)
Part No.	T01-3990-51	4N024UL
Minimum Detectable Conc.	0.11 μg/mL	0.25 μg/mL
Precision	(Total) 5.5% @ 1.7 μg/mL 4.3% @ 4.2 μg/mL 6.5% @ 8.7 μg/mL	(Between-Run) 3.9% @ 1.7 μg/mL 4.5% @ 4.5 μg/mL 4.5% @ 10.8 μg/mL
Correlation	$y = 0.99x - 0.03$ where y = Immuno 1 N-Acetylprocainamide Assay x = Syva EMIT® N-Acetylprocainamide Assay* n = 99 r = 0.99 S_{yx} = 0.29 μg/mL	

*This assay was performed on COBAS FARA II® Instrument using parameters and protocol specified in Behring Application Sheet.

Gabriel J. Muraca, Jr.

5/7/97

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

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 1997

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

Re: K971713
N-Acetylprocainamide Assay for the Bayer Immuno 1™ System
Regulatory Class: II
Product Code: LAN
Dated: May 7, 1997
Received: May 9, 1997

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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):_____

Device Name: N-Acetylprocainamide (NAPA)

Indications For Use:

This *in vitro* diagnostic procedure is intended to quantitatively measure N-acetylprocainamide, an antiarrhythmic drug, in human serum or plasma (lithium heparin) using EMIT* (Enzyme Multiplied Immunoassay Technique) technology on a *Bayer Immuno 1*™ system. Measurements of N-acetylprocainamide are used in the diagnosis and treatment of procainamide overdose and in monitoring serum or plasma levels of N-acetylprocainamide to ensure appropriate therapy. This diagnostic method is not intended for use on any other system.

(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 K017713

Prescription Use ✓ **OR** **Over-The-Counter Use**____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)