Attachment 3

SEP 22 1997

SUMMARY OF SAFETY AND EFFECTIVENESS K972580

Submitter: Mr. Gabriel J. Muraca, Jr.
Manager, Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Gabriel J. Muraca, Jr.
7/7/97

DEVICE: Deoxypyridinoline Assay for the *Bayer Immuno 1™ System*

PREDICATE DEVICE:

Name: Pyrilinks® -D
Manufacturer: Metra Biosystems, Inc.
Mountain View, CA

INTENDED USE

This *in vitro* diagnostic method is intended to quantitatively measure deoxypyridinoline (DPD) in human urine on the *Bayer Immuno 1™* system. Measurements obtained by this device are used as an indicator of bone resorption. Results obtained using the Bayer Immuno 1 system Deoxypyridinoline method are generally expressed as a ratio to urine creatinine (nM DPD/mM creatinine), and should be interpreted in conjunction with all other available clinical and diagnostic results. The urine creatinine result (mmol/L) must be entered from an off-system standard laboratory analysis.

PRINCIPLE OF THE PROCEDURE

The IMMUNO 1 DPD assay is a heterogeneous competitive immunoassay format.

PERFORMANCE CHARACTERISTICS

Sensitivity: Minimum Detectable Concentration

The minimum detectable concentration is 0.8 nM. This is a multisystem estimate of two times the within run standard deviation of the zero calibrator.

Imprecision

Within run and total imprecision were evaluated for the IMMUNO 1 DPD assay over a 10 day period using two IMMUNO 1 instruments (20 runs total). Three controls were assayed in duplicate for each run making a total of 40 assays. The results are summarized in the following table:

IMPRECISION of IMMUNO 1 DPD Method

LEVEL (nmol/L)	TOTAL SD (nmol/L)	TOTAL CV (%)	WITHIN-RUN SD (nmol/L)	WITHIN-RUN CV (%)
55.8	4.2	7.6	2.2	3.9
113.7	8.2	7.2	0.8	0.7
282.6	12.1	4.3	4.8	1.7

Method Comparison

A total of 341 human urine samples were assayed by the IMMUNO 1 DPD method and the Pyrilinks® -D method. Urine samples were clarified by centrifugation prior to assay on the IMMUNO 1. The following table lists the correlation results:

CORRELATION DATA

COMPARATIVE SYSTEM OR METHOD	N	REGRESSION EQUATION (Y=)	r	Syx (nmol/L)	RANGE OF ANALYTE CONC. (nmol/L)
Metra Pyrilinks-D®	341	1.1x + 8.4	0.98	25.6	1.1 - 924

Recovery

Eleven urine samples with endogenous DPD levels ranging from 0 nM to 158.5 nM were spiked with 100 nM DPD and the recovered DPD was determined using the IMMUNO 1 DPD method. The recovery results ranged from 96% to 110% with an average of 101.7% ± 3.8%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Gabriel J. Muraca, Jr.
Manager, Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: K972580/S1
Deoxypyridinoline Assay for the Bayer Immuno 1™ System
Regulatory Class: II
Product Code: JMM, JIS, JJX
Dated: September 10, 1997
Received: September 11, 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 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):_____

Device Name: Deoxypyridinoline (DPD)

Indications For Use:

This *in vitro* diagnostic method is intended to quantitatively measure deoxypyridinoline (DPD) in human urine on the Bayer Immuno 1™ system. Measurements obtained by this device are used as an indicator of bone resorption. Results obtained using the Bayer Immuno 1 system Deoxypyridinoline method are generally expressed as a ratio to urine creatinine (nM DPD/mM creatinine), and should be interpreted in conjunction with all other available clinical and diagnostic results. The urine creatinine result (mmol/L) must be entered from an off-system standard laboratory analysis.

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)

Carol Benson for Alfred Montgomery

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K972580

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)