

NOV 24 1999

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## 510(k) Safety and Effectiveness Summary

Prepared: July, 1999

Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P. O. Box 70  
Elkhart, Indiana 46515-0070

Contact: Syed Ataullah  
Manager, Regulatory Compliance  
219-262-6865

Device: Trade/Proprietary Name: "NEW MULTIPLES" Reagent Strips  
Common/Usual Name: Multiple Reagent Strips for Urinalysis  
Document Control Number: K99 2257

Classification: Division of Clinical Laboratory Devices  
Panel - Clinical Chemistry and Toxicology  
Classification Code - 75 JIR (Urinary protein or albumin) Class 1  
75 JFY (Creatinine, enzymatic) Class 2

Predicate Device(s): MULTISTIX® 10 SG Reagent Strips  
MICROALBUSTIX™ Reagent Strips  
CLINITEK® Microalbumin Reagent Strips

### Device Description:

Bayer's "NEW MULTIPLES" Reagent Strips are firm plastic strips for urinalysis that contain reagent areas for low level protein (15 mg/dL albumin), high level protein (>30 mg/dL protein), creatinine, blood, glucose, ketone (acetoaceticacid), nitrite, pH, specific gravity, bilirubin, and urobilinogen. A protein-to-creatinine ratio is also determined. New Multiples Reagent Strips are manually dipped into a urine specimen and "read" visually using a color chart. "NEW MULTIPLES" Reagent Strips may also be read instrumentally, using the CLINITEK® family of Urine Chemistry Analyzers. The method is designed for use with random, overnight or timed specimens. Semi-quantitative results are available within one minute.

#### Intended Use:

Reagent Strips are intended for use in at-risk patient groups to assist diagnosis in the following areas: kidney function, carbohydrate metabolism (e.g., diabetes mellitus), urinary tract infections and liver function. The reagent strips also measure physical characteristics, including acid-base balance and urine concentration. The test results can be used along with other diagnostic information to rule out certain disease states.

#### Technological Characteristics:

Bayer's "NEW MULTIPLES" Reagent Strips include new reagent areas for determination of proteinuria. A new protein reagent allows "low level" detection of albumin at 15 mg/dL in addition to the current protein reagent used for detection of "high level" protein at 30 mg/dL. A new creatinine reagent is used that measures creatinine levels from 10 to 300 mg/dL. The protein-to-creatinine ratio is reported as Normal and Abnormal.

The assay for low level protein (albumin) is based on dye binding using the high affinity dye, Bis(3',3''-diiodo-4',4''-dihydroxy-5',5''-dinitrophenyl)-3,4,5,6-tetrabromosulfonephthalein). At a constant pH, the development of a blue color is owing to the presence of albumin; the intensity of the color is proportional to the albumin concentration. The assay for creatinine is based on the peroxidase-like activity of copper creatinine complexes that catalyze the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethyl-benzidine.

#### Assessment of Performance:

The performance of Bayer's "NEW MULTIPLES" Reagent Strips was studied (visually and instrumentally using a family of CLINITEK® Analyzers) in clinical setting by typical users. The results were compared to current MULTISTIX® 10 SG Reagent Strips and commonly used laboratory methods. The studies demonstrated that typical users in centralized and point-of-care laboratories can obtain clinical test results that are comparable to commonly used laboratory methods.

#### Conclusion:

Bayer's "NEW MULTIPLES" Reagent Strips have been developed for urinalysis with the currently used reagent areas and new protein-low, protein-high, and creatinine reagent pads. The "NEW MULTIPLES" Reagent Strips are for use in near-patient (point-of-care) and centralized laboratory locations. Studies show that the product provides clinical results comparable to other test methods in current clinical practice.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NOV 24 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Syed Ataulah  
Manager, Regulatory Compliance  
Bayer Corporation  
Business Group Diagnostics  
1884 Miles Avenue, P.O. Box 70  
Elkhart, Indiana 46515-0070

Re: K992257  
Trade Name: "NEW MULTIPLES" Reagent Strips  
Regulatory Class: II  
Product Code: JFY, JIL  
Regulatory Class: I  
Product Code: JIR, CEN, JRE, JJB, JIO, JIN, JMT, CDM, KQO  
Dated: October 18, 1999  
Received: October 20, 1999

Dear Mr. Ataulah:

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.

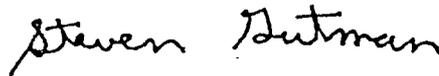
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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

510(k) Number (if known): K992257

Device Name: "NEW MULTIPLES" Reagent Strips

**Indications for Use:**

Bayer's "NEW MULTIPLES" Reagent Strips are firm plastic strips that contain reagent areas to test for low level protein (15 mg/dL albumin), high level protein (>30 mg/dL protein), creatinine, occult blood, glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, specific gravity, bilirubin, and urobilinogen. A protein to creatinine ratio is also determined. The strips are read visually by comparison to a color chart on the bottle label. The "NEW MULTIPLES" Reagent Strips can also be read instrumentally on the CLINITEK®50, CLINITEK® 100, CLINITEK® 200+ and CLINITEK® 500 Urine Chemistry Analyzers.

Bayer's "NEW MULTIPLES" Reagent Strips are intended for use in at-risk patient groups to assist diagnosis in the following areas: kidney function, carbohydrate metabolism (e.g., diabetes mellitus), urinary tract infections and liver function. The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states. Bayer's "NEW MULTIPLES" Reagent Strips are for professional use in Point -Of-Care locations such as physicians offices or clinics and centralized laboratory locations such as in hospitals.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Coopy  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K992257

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)