

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: April 15, 1999

Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515
(219) 262-6928

Contact: George M. Tancos, R.A.C.
Manager, Regulatory Compliance

Device: Trade/Proprietary Name: MICROALBUSTIX™ Reagent Strips (OTC)
Common/Usual Name: Test for albumin in urine
Test for creatinine in urine
Document Control Number: K99 1315

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code: 75 JIR [Protein or Albumin (Urinary, Non-Quantitative)]
75 JFY (Creatinine, enzymatic)

Predicate Devices: MICROALBUSTIX™ Reagent Strips (Professional)
Manufactured by Bayer Corporation

Device Description: MICROALBUSTIX Reagent Strips (OTC) are firm plastic strips that contain two reagent areas to test for microalbumin (low concentration of albumin) and creatinine in urine. MICROALBUSTIX Reagent Strips (OTC) are dipped into a urine specimen and “read” visually by comparing the color of the strip to a color chart on the label. In addition to providing an albumin and a creatinine result, an albumin-to-creatinine ratio can also be determined. Semi-quantitative results are available within one minute.

Intended Use: MICROALBUSTIX Reagent Strips (OTC) are intended for home use by testing persons at risk for developing kidney damage [REDACTED]

Technological Characteristics:

MICROALBUSTIX Reagent Strips (OTC) are dip-and-read reagent strips to detection urinary albumin at 20 to 40 mg/L, and the albumin-to-creatinine ratio of 30 to 300 mg/g. The albumin test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of a blue color is due to the presence of albumin. The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The color of the reagent areas are read visually by comparing to a color chart on the label. The albumin-to-creatinine ratio is determined according to a table in the package insert.

Assessment of Performance:

The performance of MICROALBUSTIX Reagent Strips (OTC) was studied in clinical and home use settings by typical lay users and results compared to currently used laboratory tests for microalbumin and creatinine in urine. The studies demonstrated that lay users can obtain clinical test results that are substantially equivalent to current methods.

Conclusion:

MICROALBUSTIX Reagent Strips (OTC) provide a convenient method for testing for microalbumin and creatinine in urine. Studies show that the product can be used by lay persons to obtain results comparable to results obtained by health care professionals.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 1999

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

Re: K991315
Trade Name: MICROALBUSTIX™ Reagent Strips (OTC)
Regulatory Class: II
Product Code: JFY
Regulatory Class: I
Product Code: JIR
Dated: August 2, 1999
Received: August 3, 1999

Dear Mr. Tancos:

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.

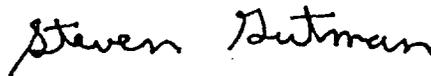
Page 2

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,



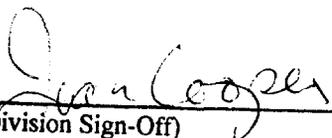
Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991315

Device Name: MICROALBUSTIX™ Reagent Strips (OTC)

Indications for Use: MICROALBUSTIX Reagent Strips (OTC) are firm plastic strips that contain two reagent areas to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. The strips are read visually by comparing the color of the reacted strip to the color chart on the bottle label. MICROALBUSTIX Reagent Strips (OTC) provide semi-quantitative results and are intended for home use by persons at risk of developing kidney disease.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991315

(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)