OCT 26 2005

K051727

510(k) Summary of Safety & Effectiveness

Device Name:	AimStick® Urine Reagent Strips
Common Name:	Urinalysis Reagent Strips
Device Description:	Plastic strips with reagent pads which provide a color change when exposed to urine.
Medical Specialty:	Clinical Chemistry
Intended Use:	The AimStick® Urine Reagent Strips are intended for detection of glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite and leukocytes in urine.
Product Description:	The AimStick® Urine Reagent Strips are plastic strips to which Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte reagent pads are affixed. The reagent pads react with the urine and provide a visible color reaction. The product is packaged with a drying agent in a plastic bottle. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. The directions must be followed exactly. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. Laboratory instrumentation is not required.

Tests Principles:

Glucose:	This test is based upon the enzymatic glucose oxidase/peroxidase (GOD/POD) method. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxidase with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to blue.
Bilirubin:	This test is based upon the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The colors produced on the reagent pad ranges through various shades of beige or tan.
Ketone:	This test is based upon the reaction between acetoacetate and sodium nitroprusside in an alkaline medium. A positive result is indicated by a color change on the reagent pad from beige to violet.
Specific Gravity:	This test is based upon the release of protons in the presence of cations. The reaction produces hydrogenous ionogen, which reacts with pH indicator. Colors produced range from deep blue-green through yellow-green.
Blood:	This test is based upon hemoglobin reacting as peroxidase. Intact erythrocytes hemolyze on the test pad and the hemoglobin released produces a green dot. Scattered green dots on the yellow test pad are indicative of intact erythrocytes. A uniform green color is indicative of released hemoglobin, myoglobin, or hemolyzed erythrocytes. The colors produced range from orange through green.
pH:	The test is based upon the well known method of pH indicators methyl red and bromthymol blue. The colors range from orange through yellow and green to blue.
Protein:	This is based upon the protein-error-of-indicator principle. Anion in the specific pH indicator attracted by cation on protein molecules makes the indicator further ionized, which changes its color. A positive reaction is indicated by a color change from yellow to light green and to darker greens.

Urobilinogen: This test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a Strongly acid medium. A positive reaction is indicated by a pink-reddish color.

Nitrite: This test is based upon the conversion of Nitrate to Nitrite. The Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change. A positive reaction is indicated by a light pink to pink color.

Leukocytes: This test is based upon the reaction of esterases, present in granulocytic leukocytes, which catalyze the hydrolysis of an indoxylcarbonic acid ester to indoxyl. A positive reaction is indicated by a light purple to dark purple color.

Substantial Equivalence: The AimStick® Urine Reagent Strips are substantially equivalent to the Bayer MultiStix® 10SG reagent strips.

Characteristics of the AimStick® Urine Reagent Strips are compared with the Bayer MultiStix® 10SG system in the following table:

Comparison of Features

Area of Comparison	AimStick® 10-SG	Bayer MultiStix® 10 SG
Intended Use	Professional use in point-of-care urine testing	Professional use in point-of-care urine testing
Target Population	Patients of physicians, hospitals, and clinics	Patients of physicians, hospitals, and clinics
Intended Specimen	Urine	Urine
Materials Provided	Plastic Strips affixed with several separate reagent areas.	Plastic Strips affixed with several separate reagent areas.
Storage	2 to 30 C	15 to 30 C
Test Time	30 Seconds – 2 Minutes	30 Seconds – 2 Minutes
Glucose Methodology	Based upon the enzymatic glucose oxidase /peroxidase (GOD/POD) method. Glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxidase with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to blue.	Based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of glucuronic acid and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen that cause the color ranges from green to brown.
Bilirubin Methodology	Based upon the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The colors	Based on the bilirubin and dichlorobenzene diazonium cupping and produces a strongly acid medium with

	produced on the reagent pad ranges through various shades of beige or tan.	colors ranges through shades of tan.
Ketone Methodology	Based upon the reaction between acetoacetate and sodium nitroprusside in an alkaline medium. A positive result is indicated by a color change on the reagent pad from beige to violet.	Based on the development of colors ranging from buff-pink for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.
Specific Gravity Methodology	Based upon the release of protons in the presence of cations. The reaction produces hydrogenous ionogen, which reacts with pH indicator. Colors produced range from deep blue-green through yellow-green.	Based on the pKa change of polyelectrolytes in relation with ionic concentration. In the presence of an indicator, colors range from deep blue-green through green and yellow-green.
Blood Methodology	Based upon hemoglobin reacting as peroxidase. Intact erythrocytes hemolyze on the test pad and the hemoglobin released produces a green dot. Scattered green dots on the yellow test pad are indicative of intact erythrocytes. A uniform green color is indicative of released hemoglobin, myoglobin, or hemolyzed erythrocytes. The colors produced range from orange through green.	Based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5' tetramethylbenzidine. The resulting color ranges from orange through green.
pH Methodology	Based upon the well known method of pH indicators methyl red and bromthymol blue. The colors range from orange through yellow and green to blue.	Based on double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
Protein Methodology	Based upon the protein-error-of-indicator principle. Anion in the specific pH indicator attracted by cation on protein molecules makes the indicator further ionized, which changes its color. A positive reaction is indicated by a color change from yellow to light green and to	Based on the protein-error-of-indicator principle. At a constant pH, the development of any green color due to the presence of protein. Colors range from yellow through yellow-green and green to green-blue.

	darker greens.	
Urobilinogen Methodology	Based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a Strongly acid medium. A positive reaction is indicated by a pink-reddish color.	Based on a modified Ehrlich reaction in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acidic medium to produce a pink-red color.
Nitrite Methodology	Based upon the conversion of Nitrate to Nitrite. The Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change. A positive reaction is indicated by a light pink to pink color.	This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. The diazonium compound couples with tetrahydrobenzo quiniolin-3ol to produce a pink color.
Leukocytes Methodology	Based upon the reaction of esterases, present in granulocytic leukocytes, which catalyze the hydrolysis of an indoxylcarbonic acid ester to indoxyl. A positive reaction is indicated by a light purple to dark purple color.	Granulocyte leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole that react with diazonium salt to produce a purple color.

Summary: A clinical trial was conducted comparing the results of the AimStick® Urine Reagent Strips to the Bayer MultiStix® 10 SG. The study included 196 urine samples that were tested with both AimStick® 10-SG and Bayer MultiStix® 10 SG. The test results were compared. Clinical study results in this 510(k) submission demonstrate that the AimStick® Urine Reagent Strips are substantially equivalent to the Bayer MultiStix® 10 SG.

Submitted by: Germaine Laboratories, Inc.
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Prepared on: June 20, 2005
By Martin O'Connor, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

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OCT 2 6 2005

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Re: k051727
Trade/Device Name: AimStick® Urine Reagent Strips
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, LJX, CEN, JMT, JIR, JIN, CDM, JJB
Dated: September 15, 2005
Received: September 20, 2005

Dear Mr. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051727

Device Name: AimStick® Urine Reagent Strips

Indications For Use: The AimStick® Urine Reagent Strips are intended for the qualitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, and Leukocytes in urine for persons to test by visual comparison with a color chart on the bottle label. This product is for professional use. Test results may provide information regarding the status of carbohydrate metabolism, kidney function, liver function, acid-base balance, and bacturia.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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