

K971976

JUN 17 1997

**Summary of Safety and Effectiveness**

**May 27, 1997**

The following information is provided as a summary of safety and effectiveness information for the DIASCREEN® Reagent Strip System.

[a] Common Name: Visual Reagent Test Strip for Urinalysis

Trade/Proprietary Name: DIASCREEN® Reagent Strips, in many different configurations with as many different product codes. DIASCREEN® is the registered trademark of Dia-Screen Corporation.

[b] Establishment Registration Number: 9010673

Chung Do Pharmaceutical Co., Ltd.  
312 Gaju-Dong Jin Hae-City  
Kyung Sang Nam-Do, 645-500 Korea.

[c] Contact Person: Vicki Frawley

[d] Intended Use

The DIASCREEN® Reagent Strip for Urinalysis is a dip-and-read test strip for semi-quantitative urinalysis. DIASCREEN® Reagent Strips have been developed to allow health care professionals to test semi-quantitatively for patient urine levels of specific gravity, ketone, glucose, protein, blood, leukocytes, nitrite, pH, bilirubin, and urobilinogen by visual comparison with a color chart.

[e] Product Description

DIASCREEN® Reagent Strips are plastic strips to which are affixed reagent test areas. Several product configurations are included with this submission, but all configurations are limited to one, some or all of the following tests: specific gravity, ketone, glucose, protein, blood, leukocytes, nitrite, pH, bilirubin, and urobilinogen.

The reagent test areas on the DIASCREEN® Reagent Strips are ready to use upon removal from the bottle and the entire reagent

strip is disposable after use. The strips are to be read visually, requiring no additional laboratory equipment for testing.

The directions must be followed exactly. Accurate timing is essential to provide optimal results. The reagent strips must be kept in the original bottle containing the desiccant with the cap tightly closed to maintain reagent activity. To obtain optimal results it is necessary to use fresh, well-mixed, uncentrifuged urine.

**The DIASCREEN® Reagent Strips will be manufactured in Korea by Chung Do Pharmaceutical CO., Ltd. of Seoul, Korea. They will be marketed in the United States by Dia-Screen Corporation. Dia-Screen is the exclusive United States distributor for Chung Do.**

**Dia-Screen Corporation has previously submitted 510k's on behalf of Chung Do Pharmaceutical Co., Ltd and Bioscan Instruments, Inc.(now defunct) under Dia-Screen Corporation's former name, Genesis Labs Inc. These are K940043 and K943008. In addition, Dia-Screen Corporation, which is a FDA registered facility, has received two 510k's for its own manufactured urine reagent strips. They are K961375 and K952971.**

**The intended use of the strips that are the subject of this new premarket notification is exactly the same as the Bioscan (K940043, K943008) and DIASCREEN® (K952971, K961375) strips which were reviewed previously.**

[f] Substantial Equivalence

The intended use of the strips which are the subject of this new pre-market notification is exactly the same as the strips which were reviewed previously (K940043, K943008, K952971, K961375).

The design and function of the new DIASCREEN® Reagent Strips are the same as the design and function of both the Bioscan and DIASCREEN® Reagent Strips which have been previously reviewed under pre-market notifications K940043, K943008, K952971, and K961375.

The DIASCREEN® Reagent Strips for Urinalysis are substantially equivalent to Bayer Multistix 10 SG, Behring Rapignost, Bioscan, and Boehringer Mannheim Chemstrip urine test strip systems.

Characteristics of the Bayer Multistix 10 SG and the Bioscan systems are compared with the DIA SCREEN® system in the following table:

Strip Name	<b>This 510 (k) DIASCREEN®</b>	<b>Prevoius 510 (k) Bioscan</b>	<b>Bayer Multistix 10 SG</b>
Distributor	Dia-Screen	Dia-Screen	Bayer
Reagents for:			
Specific Gravity	Bromothymol blue Methyl red Polyvinyl phosphate	Bromthymol blue Methyl vinyl ether/ maleic acid copolymer	Bromthymol blue Poly (methyl vinyl-ether maleic anhydride)
Leukocyte	2-Phenylthiazole amino acid ester Diazonium salt	Not offered	Derivatized pyrrole amino acid ester Diazonium salt Buffer
Ketones	Sodium nitroprusside	Sodium nitroprusside	Sodium nitroprusside Buffer
Glucose	Glucose oxidase Peroxidase Potassium iodide	Glucose oxidase Peroxidase Potassium iodide	Glucose oxidase Peroxidase Potassium iodide Buffer
Protein	Tetrabromphenol blue Citric acid Trisodium citrate	Tetrabromphenol blue Citric acid Trisodium citrate	Tetrabromphenol blue Buffer
Blood	2,5 Dimethylhexane- 2,5-dihydroperoxide 3,3',5,5'- Tetramethylbenzidine	2,5 Dimethylhexane- 2,5-dihydroperoxide 3,3',5,5'- Tetramethylbenzidine	Diisopropylbenzene- dihydroperoxide 3,3',5,5'- Tetramethylbenzidinel

Strip Name	<b>This 510 (k)</b> <b>DIASCREEN®</b>	<b>Prevoius 510 (k)</b> <b>Bioscan</b>	<b>Bayer Multistix 10 SG</b>
Distributor	Dia-Screen	Dia-Screen	Bayer
Reagents for:			
Nitrite	p-Arsanilic acid N-(1-naphthyl)ethylene diamine	p-Arsanilic acid N-(1-naphthyl)ethylene diamine	p-Arsanilic acid 1,2,3,4-Tetrahydro- benzo(h)quinoline-3-ol Buffer
pH	Bromthymol blue Methyl red	Bromthymol blue Methyl red	Bromthymol blue Methyl red
Bilirubin	2,4 Dichlorobenzene- diazonium salt Oxalic acid	2,4 Dichlorobenzene- diazonium salt Oxalic acid	2,4-Dichloroaniline- diazonium salt Buffer
Urobilinogen	4-methoxybenzene- diazonium salt Citric acid	4-methoxybenzene- diazonium salt Citric acid	Diethylaminobenzaldehyde

	<b>This 510 (k)</b>	<b>Previous 510 (k)</b>	
Strip Name	<b>DIA SCREEN®</b>	<b>Bioscan</b>	<b>Multistix 10 SG</b>
Distributor	Dia-Screen	Dia-Screen	Bayer
Packaged with Desiccant	Yes	Yes	Yes
Control Available	Yes	Yes	Yes
Time required to read strips	10 to 120 seconds	60 seconds	30 to 120 seconds
Storage	Between 15 - 30 °C (59°- 86° F). Do Not Store in refrigerator or freezer. Do not expose to moisture, heat or light.	Between 15 - 30 °C (59°- 86° F). Do Not Store in refrigerator or freezer. Do not expose to moisture, heat or light	Between 15°- 30° C (59°- 86° F) Do Not Store in Direct Sunlight

Strip Name	<b>This 510 (k)</b> <b>DIA SCREEN®</b>	<b>Previous 510 (k)</b> <b>Bioscan</b>	<b>Multistix 10 SG</b>
Distributor	Dia-Screen	Dia-Screen	Bayer
<b>Expected Values:</b>			
Specific Gravity	Random urines vary from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022	Random urines vary from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022	Random urines vary from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022
Ketones	Should not be detected in normal urine.	Should not be detected in normal urine.	Normal specimens yield negative results.
Glucose	None found in normal urine. Concentrations of 100 mg/dL may be considered abnormal.	None found in normal urine. Concentrations of 100 mg/dL may be considered abnormal.	None found in normal urine. Concentration of 100 mg/dL may be considered abnormal.
Protein	Normal specimens ordinarily contain some protein (0-4 mg/dL). Persistent results of trace or higher indicate significant proteinuria.	Normal specimens ordinarily contain some protein (0-4 mg/dL). Persistent results of trace or higher indicate significant proteinuria.	Normal specimens ordinarily contain some protein (0-4 mg/dL). A color matching any "+" block indicates significant proteinuria

Strip Name	<b>This 510 (k) DIA SCREEN®</b>	<b>Previous 510 (k) Bioscan</b>	<b>Multistix 10 SG</b>
Distributor	Dia-Screen	Dia-Screen	Bayer
<b>Expected Values:</b>			
Blood	The practical detection limit of this test is 5 to 10 erythrocytes per microliter of urine	The practical detection limit of this test is 5 to 10 erythrocytes per microliter of urine	The significance of the trace reaction may vary among patients. Clinical judgement is required
Nitrite	Any degree of pink color after 30 seconds indicates clinically significant bacteria	Any degree of pink color after 30 seconds indicates clinically significant bacteria NA	Normally, no nitrite is detectable in urine
pH	Normal urine has a pH of 6 and urine pH values generally range from 5 to 8	Normal urine has a pH of 6 and urine pH values generally range from 5 to 8NA	Both the normal and abnormal pH range is from 5 to 9 pH units
Bilirubin	No bilirubin is detectable in urine of healthy persons	No bilirubin is detectable in urine of healthy persons	Normally, no bilirubin is detectable in healthy persons
Urobilinogen	Normal range is 0.1 to 1.0 mg/dL	N Normal range is 0.1 to 1.0 mg/dL A	Normal range is 0.1 to 1.0 Ehrlich units per 100 ml

## Clinical Laboratory Evaluation of DIASCREEN® Strips

The DIASCREEN® Reagent Strip for Urinalysis is a dip-and-read test strip intended for use as an in-vitro diagnostic aid using urine specimens. DIASCREEN® Reagent Strips have been developed to allow health care professionals to semi-quantitatively determine levels of specific gravity, ketone, glucose, protein, blood, leukocytes, nitrite, pH, bilirubin, and urobilinogen in patient urine by visual comparison with a color chart of each concentration range. No additional reagents or laboratory equipment are required. These reagent strips are packaged in a plastic vial containing a desiccant. The test strips must be maintained tightly capped in the plastic vial to assure reagent activity. The directions-for-use must be followed exactly.

An independent laboratory evaluation of the new DIASCREEN® Reagent Strips for Urinalysis was conducted under the direction of James Jackson MT(ASCP) CLS, Ph.D. at Wichita State University Department of Medical Technology. The purpose of the laboratory evaluation was to establish the performance of the leukocyte and specific gravity tests and to evaluate the pH, nitrite and blood for placement adjacent to these tests on the DIASCREEN® Reagent Strip for Urinalysis when compared to a "510 (k) approved" marketed urinalysis strip system.

The study consisted of comparing the performance of two (2) manufactured lots of DIASCREEN® Reagent Strips with the marketed product (Bayer Multistix 10 SG).

Fresh urine samples were obtained at the medical facility. The comparison strips, Bayer Multistix 10 SG Reagent Strips, Schein Urispec Reagent Strips(for ascorbic acid detection), Boehringer Manneheim Corporation CHEMSTRIP Reagent Strips(for confirmatory testing), normal and abnormal urine controls were furnished by Dia-Screen. When data between the two products did not agree within one color block, an alternate procedure (see table below) was used to test the sample.

Analyte	Confirmation Test	Manufacturer
Specific Gravity	Refractometer	NA
Leukocyte	Microscopic Evaluation CHEMSTRIP	NA Boehringer Mannheim
pH	pH Meter	NA
Blood	Microscopic Evaluation CHEMSTRIP Ascorbic Acid Test/Urispec	NA Boehringer Mannheim Henry Schein
Nitrite	Microscopic Evaluation CHEMSTRIP	NA Boehringer Mannheim

Fresh, well-mixed, and uncentrifuged urine from a mixed patient population was reacted with the DIASCREEN® Reagent Strips and the results were read by visual comparison with the DIASCREEN® color chart. Results of these readings were compared to results measured by Multistix 10 SG Reagent Strips.

A summary of the data obtained from the clinical evaluation described above is provided in the following tables.

## DIASCREEN® versus Bayer Clinical Correlation

Tables I and II present the percentage of responses for the indicated lots of the DIASCREEN® and Bayer Reagent Strips that are within the same color block and that are within plus or minus one color block. Table III presents a similar analysis for the two lots of the DIASCREEN® Reagent Strips.

Table I. DIASCREEN® Lot 1 versus Bayer Lot D639066 or 6K30C

	Same Color Block		Within 1 Color Block	
Specific Gravity	39/53	74%	53/53	100%
Leukocyte	42/53	79%	53/53	100%
pH	37/53	70%	53/53	100%
Blood	49/53	92%	53/53	100%
Nitrite	53/53	100%	53/53	100%

Table II. DIASCREEN® Lot 2 versus Bayer Lot D639066 or 6K30C

	Same Color Block		Within 1 Color Block	
Specific Gravity	35/53	66%	53/53	100%
Leukocyte	43/53	81%	53/53	100%
pH	35/53	66%	53/53	100%
Blood	44/53	83%	53/53	100%
Nitrite	53/53	100%	53/53	100%

Table III. DIASCREEN® Lot 1 versus DIASCREEN® Lot 2

	Same Color Block		Within 1 Color Block	
Specific Gravity	48/53	91%	53/53	100%
Leukocyte	47/53	89%	53/53	100%
pH	49/53	92%	53/53	100%
Blood	52/53	98%	53/53	100%
Nitrite	53/53	100%	53/53	100%



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 17 1997

John Murray  
• President and Chief Executive Officer  
Dia-Screen Corporation  
5182 West 76th Street  
Minneapolis, Minnesota 55439

Re: K971976  
DIASCREEN® 10 Way Reagent Strips for Urinalysis  
(In Duplicate)  
Regulatory Class: I & II  
Product Code: LJX, JNA, KQO  
Dated: May 27, 1997  
Received: May 29, 1997

Dear Mr. Murray:

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.

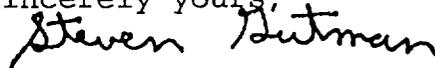
Page 2

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/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

O(k) Number (if known): K971976

Device Name: DIASCREEN Reagent Strips

Indications For Use:

The DIASCREEN® Reagent Strip for Urinalysis is a dip-and-read test strip and is intended for use as an *in vitro* diagnostic aid using urine specimens. The strip contains solid phase reagent areas affixed to a plastic strip and is provided in a dry reagent format.

The strip provides qualitative and semi-quantitative tests for specific gravity, ketones, glucose, protein, blood, leukocytes, nitrite, pH, bilirubin, and urobilinogen by visual comparison with a color chart for each concentration range. No additional reagents and laboratory equipment are required. The reagent strips are packaged in a plastic vial containing a desiccant. The

test strips must be kept tightly capped in the vial to assure reagent reactivity. The directions must be followed exactly and it is necessary to use fresh, well-mixed, uncentrifuged urine for optimal results.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Veronica Calvia for Dr. D. Montgomery*  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K971976

Prescription Use    
 (21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)