JUN 11 1998

K981555

Summary of Safety and Effectiveness

April 22, 1998

The following information is provided as a summary of safety and effectiveness information for the DIASCREEN® Reagent Strip System. The reagent strips which are the subject of this pre-market notification contain one new reagent area for leukocytes in urine. The other nine reagent areas have been previously reviewed.

[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: 2183670

Chronimed Inc.
Bury Drive
Eden Prairie, MN 55346

[c] Contact Person:

Vicki Frawley
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Minneapolis, MN 55439
Phone: (612) 835-3446 ext. 17
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[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.

Dia-Screen Corporation has previously received a determination of substantial equivalence for complete lines of reagent strips for urinalysis which have been marketed under the Bioscan label (K940043) and the DIASCREEN® label (K952971, K961375). The intended use of the strips that are the subject of this new premarket notification is exactly the same as the Bioscan (K940043) and DIASCREEN® (K952971, K961375) strips which were reviewed previously.

Chronimed Inc. purchased Dia-Screen Corporation on March 16, 1998. The DIASCREEN® Reagent Strips will be manufactured by Chronimed Inc. for distribution by Chronimed Inc.

[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, K971976).

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, K961375, and K971976.

The DIASCREEN® Reagent Strips for Urinalysis are substantially equivalent to the previous line of DIASCREEN® Reagent Strips (K943008, K961375) and the Bayer Multistix 10 SG Reagent Strips for Urinalysis. The new reagent area for leukocytes in urine on the DIASCREEN® Reagent Strips is substantially equivalent to the reagent area for leukocytes in urine on the Bayer Multistix 10 SG reagent strips.

Characteristics of the Bayer Multistix 10 SG system and the previous DIASCREEN® system are compared with the subject DIASCREEN® system in the following table.

	This 510 (k)	Prevoius 510 (k)	
Strip Name	**DIASCREEN®**	**DIASCREEN®**	**Bayer Multistix 10 SG**
Distributor	Dia-Screen	Dia-Screen	Bayer
Reagents for:			
Leukocyte	2-(3-Methoxyphenyl)-4-thiazol Diazonium salt	Not offered	Derivatized pyrrole amino acid ester Diazonium salt Buffer
Specific Gravity	Bromothymol blue Methyl red Polyvinyl phosphate	Bromthymol blue Detergent	Bromthymol blue Poly (methyl vinyl-ether maleic anhydride)
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

	This 510 (k)	Prevoius 510 (k)	
Strip Name	**DIASCREEN®**	**DIASCREEN®**	**Bayer Multistix 10 SG**
Distributor	Dia-Screen	Dia-Screen	Bayer
Reagents for:			
Nitrite	p-Arsanilic acid Hydroxy(3)-1,2,3-tetrahydrobenzo(h)quinoline	p-Arsanilic acid Hydroxy(3)-1,2,3-tetrahydrobenzo(h)quinoline	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 Sulfasalicylic acid	2,4 Dichlorobenzene-diazonium salt	2,4-Dichloroaniline-diazonium salt Buffer
Urobilinogen	4-methoxybenzene-diazonium salt Metaphosphoric acid	Dimethylaminobenzaldede	Diethylaminobenzaldede

	This 510 (k)	**Previous 510 (k)**	
Strip Name	**DIA SCREEN®**	**DIA SCREEN®**	**Multistix 10 SG**
Distributor	Dia-Screen	Dia-Screen	Bayer
Packaged with Desiccant	Yes	Yes	Yes
Control Available	Yes	Yes	Yes
Time required to read strips	30 to 120 seconds	30-60 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

	This 510 (k)	Previous 510 (k)	
Strip Name	**DIA SCREEN®**	**DIA SCREEN®**	**Multistix 10 SG**
Distributor	Dia-Screen	Dia-Screen	Bayer
Expected Values:			
Leukocyte	Normally no leukocytes are detected in urine. Individually observed trace results may be of questionable clinical significance. Positive results found in random specimens from females may be due to vaginal contamination.	Not applicable.	Normal urine specimens generally yield negative results. Positive results (small or greater) are clinically significant. However, trace results observed repeatedly may be clinically significant/ Positive and repeated trace results indicate the need for testing of the patient and/or urine specimen according to medically accepted procedures for pyuria. Positive results may be found with random specimens from females due to contamination by vaginal discharge.

	This 510 (k)	Previous 510 (k)	
Strip Name	**DIA SCREEN®**	**DIA SCREEN®**	**Multistix 10 SG**
Distributor	Dia-Screen	Dia-Screen	Bayer
Expected Values:			
Leukocyte	Normally no leukocytes are detected in urine. Individually observed trace results may be of questionable clinical significance. Positive results found in random specimens from females may be due to vaginal contamination.	Not applicable.	Normal urine specimens generally yield negative results. Positive results (small or greater) are clinically significant. However, trace results observed repeatedly may be clinically significant/ Positive and repeated trace results indicate the need for testing of the patient and/or urine specimen according to medically accepted procedures for pyuria. Positive results may be found with random specimens from females due to contamination by vaginal discharge.

	This 510 (k)	Previous 510 (k)	
Strip Name	**DIA SCREEN®**	**DIA SCREEN®**	**Multistix 10 SG**
Distributor	Dia-Screen	Dia-Screen	Bayer
Expected Values:			
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

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, leukocyte, ketone, glucose, protein, blood, 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.

Two independent laboratory evaluations of the DIASCREEN® Urine Leukocyte Test were conducted. The purpose of the laboratory evaluations was to establish the performance of the leukocyte test when compared to a "510(k) approved" marketed urinalysis strip system.

Clinical Evaluation One was under the direction of James Jackson, MT(ASCP) CLS, Ph.D. at Wichita State University Department of Medical Technology (Site 1). The study consisted of comparing the performance of two (2) manufactured lots of DIASCREEN® Leukocyte 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, were furnished by Dia-Screen.

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.

Clinical Evaluation Two was conducted under the direction of Myron Rapkin, Technovations Inc. at two clinical sites. Reagent strips and urine samples were handled as described above.

A summary of the data obtained from the two clinical evaluations follows. Table I presents the percentage of responses of the DIASCREEN® Strips that are within the same color block and that are within plus or minus one color block of Bayer Leukocyte results. Table II presents a similar analysis for two lots of the DIASCREEN® Reagent Strips tested during Clinical Evaluation One. The data used to compile these tables is presented for each evaluation in charts where the shaded region represents the within plus or minus one color block range.

DIASCREEN® versus Bayer Clinical Correlation

Table I. DIASCREEN® Lot 1 versus Bayer Multistix

	Same Color Block			Within 1 Color Block	
Evaluation One-Lot 1	35/39	90%		39/39	100%
Evaluation One-Lot 2	35/39	90%		39/39	100%
Evaluation Two	237/279	85%		268/279	96%

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

Evaluation One-	Same Color Block			Within 1 Color Block	
Lot 1 vs Lot 2	35/39	87%		39/39	100%

510(k) Number (if known): K981555

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)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981555

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 1998

Vicki Frawley
Chronimed Inc.
5182 West 76th Street
Minneapolis, Minnesota 55439

Re: K981555
DIASCREEN® Leukocyte Reagent Strip for Urinalysis
Regulatory Class: II
Product Code: LJX
Dated: April 22, 1998
Received: May 1, 1998

Dear Ms. Frawley:

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): K981555

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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