K981084

OCT 7 1998

510(k) Summary

Date of Summary: March 21, 1998

Product Name:
Uriscreen

Sponsor's Name:
Diatech Diagnostics, Inc.
90 Windom Street
Boston, MA 02134

CORRESPONDENT:
MDC ASSOCIATES
Fran White
Regulatory Consultant
15 Oak Street
Beverly Farms, MA 01915

SUBSTANTIALLY EQUIVALENT DEVICES:

Product: MULTISTIX- Reagent Strip for Urinalysis
Manufactured by: Bayer Diagnostics

Product: Uri-Test - Nitrite in Urine Test
Manufactured by: Technical Chemical and Product Inc.

PRODUCT DESCRIPTION:

Uriscreen - Uriscreen is a rapid screen for the detection of Urinary Tract Infection. Uriscreen detects Catalase activity. Most organisms that commonly cause Urinary Tract Infection are Catalase positive. Additionally, Catalase activity is an indicator of white blood cells in urine. White blood cells are a common indicator of Urinary Tract Infection.

INTENDED USE:

Uriscreen is a non-quantitative rapid screen for the detection of Urinary Tract Infection. Uriscreen detects both bacteria and/or white blood cells, common indicators of Urinary Tract Infection.

SUMMARY OF TECHNOLOGY:

Uriscreen tubes contain a reagent powder, which enables Catalase detection. Urine is added to the tube to the line indicated, a few drops of hydrogen peroxide solution are added. Production of foam indicates Catalase activity. Catalase activity is indicative of bacteria and/or white blood cells in the urine. Most bacteria that commonly cause urinary tract infection are Catalase positive. The presence of bacteria and/or white blood cells in the urine are clearly indicative of Urinary Tract Infection.

PERFORMANCE DATA:

A clinical trial was done to compare the performance of the Uriscreen to Bayer Multistix Leukocyte esterase/Nitrite and the Uri-Test Nitrite in Urine. These data clearly demonstrate that the performance of the Uriscreen test is substantially equivalent to the predicate devices.

Phase I

Multistix Nitrite/LE vs. Uriscreen

	Multistix +	Multistix -
Uriscreen +	13	10
Uriscreen -	0	69
	Sensitivity =	**100.00%**
	Specificity =	**87.34%**
	Accuracy =	**89.13%**

Uri-Test Nitrite in Urine vs. Uriscreen

	Nitrite +	Nitrite -
Uriscreen +	12	9
Uriscreen -	3	68
	Sensitivity =	**80.00%**
	Specificity =	**88.31%**
	Accuracy =	**86.96%**

Uriscreen was also compared to reference culture method.

Culture vs. Uriscreen

	Culture +	Culture -
Uriscreen +	11	12
Uriscreen -	0	69

Sensitivity = 100.00%
Specificity = 85.19%
Accuracy = 86.96%

Uriscreen was performed by consumers on their own urine. Data confirm that Uriscreen is easy to use and can be effectively used by consumers with no training or instructions.

Phase II

To demonstrate the ease-of-use and the ability for the lay consumer to perform and interpret the Uriscreen test, we asked participants at a social club and MDC Associates to test blinded samples. We recruited 65 consumers to read the Uriscreen Package Insert, perform the test on a blinded sample and interpret the results. The blinded samples consisted of a negative, which contained water only and the positive sample contained water and yeast at 10^5 CFU/ml. All consumer results were confirmed by a trained Medical Technologist. 100% accuracy was observed.

Consumer vs. Medical Technologist

	Uriscreen + (Med Tech)	Uriscreen - (Med Tech)	Row Total
Uriscreen + (consumer	32	0	32
Uriscreen - (consumer)	0	33	33
Total	32	33	65

Sensitivity = 100.00%
Specificity = 100.00%
Accuracy = 100.00%

Phase III

To demonstrate the performance of the Uriscreen test, an Accuracy and Outcome Analysis study was done in three CLIA Registered Clinical Laboratories. Only patients presenting with symptom of Urinary Tract Infection were included in the study.

Uriscreen test results were compared to culture, and based on our protocol criteria a positive culture is considered ≥100,000 CFU/ml.

Uriscreen vs. Culture
(≥100,000)

	Culture +	Culture -	Row Total
Uriscreen +	41	26	67
Uriscreen -	2	70	72
Total	43	96	139

Sensitivity =	95.35%
Specificity =	72.92%
Accuracy =	79.86%

Leukocyte esterase (LE) vs. Culture
(≥100,000)

	Culture +	Culture -	Row Total
LE +	38	43	81
LE -	4	54	58
Total	42	97	139

Sensitivity =	90.48%
Specificity =	55.67%
Accuracy =	66.19%

Nitrite vs. Culture
(≥100,000)

	Culture +	Culture -	Row Total
Nitrite +	16	2	18
Nitrite -	27	94	121
Total	43	96	139

Sensitivity =	37.21%
Specificity =	97.92%
Accuracy =	79.14%

Based on our protocol criteria, a positive culture would have significant growth of ≥100,000. Uriscreen demonstrates 95% Sensitivity when compared to positive culture. Leukocyte esterase only demonstrates 90% Sensitivity when compared to positive culture and Nitrite is only 37% Sensitive.

Uriscreen vs. Culture (≥10,000 to >100,000)

	Culture – Positive	Culture - Neg	Row Total
Uriscreen - Pos	58	9	67
Uriscreen - Neg	13	59	72
Total	71	68	139

Sensitivity =	82%
Specificity =	87%
Accuracy =	84%

Uriscreen demonstrates a specificity of 87% and a sensitivity of 82% at $10^3 - 10^5$ CFU/ml.

There are 9 specimens with negative culture results (No Growth) and positive Uriscreen results. The Uriscreen test will produce a positive result if other cells are present in the urine. Of the 9 positive Uriscreen/No Growth cultures, 6 were reported to have White blood cells or blood in the urine.

Uriscreen is a better indicator of UTI than either Leukocyte esterase (Sensitivity 90%) or Nitrite (Sensitivity 37%) based on positive culture results ($\geq$100,000). When you look at culture growth from $\geq$10,000 to $\geq$100,000 Uriscreen sensitivity is 82%, but the specificity is 87%.

STATEMENT OF SAFETY AND EFFICACY:

When compared to a Bayer Multistix and the Uriscreen was performed by untrained consumers, the product performance was as follows:

Sensitivity - 100%
Specificity - 87
Accuracy - 89%

When the Uriscreen test performed by the lay consumer and was compared to Uri-Test Nitrite in Urine, the performance of the Uriscreen test was as follows:

Sensitivity - 80%
Specificity - 88%
Accuracy - 87%

When the Uriscreen test performed by the lay consumer was compared to culture, performance was as follows:

Sensitivity - 100%
Specificity - 85%
Accuracy - 87%

When Uriscreen was tested in three clinical laboratories, comparing Uriscreen test results to reference culture results, performance was as follows:

Sensitivity – 95%
Specificity – 73%
Accuracy – 80%

These data clearly demonstrate the safety and efficacy of Uriscreen.
Uriscreen was performed by consumers on their own urine. Data confirm that Uriscreen is easy to use and can be effectively used by consumers with no training or instructions.

Diatech Diagnostics, Inc. confirm that any/all data provided in this submission may be released upon request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 7 1998

Diatech Diagnostics, Inc.
c/o Fran White
Regulatory Consultant
MDC Associates
15 Oak Street
Beverly Farms, MA 01915

Re: K981084
Trade Name: Uriscreen - A Rapid Screen for Catalase
Regulatory Class: I
Product Code: JXA
Dated: September 1, 1998
Received: September 2, 1998

Dear Ms. White:

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 at (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

Statement
Indication of Use

510(k) Number: K981084
Device Name: Uriscreen - a rapid screen for catalase.

Indication for Use:

Uriscreen is a non-quantitative rapid screen, which detects catalase. Urinary catalase may be associated with White Blood Cells, bacteria and other cells, some of which may be indicators of urinary tract infection. Only Adults should use the test.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 981084

☐ Prescription Use (Per 21 CFR 801.109) OR ☒ Over-The-Counter Use (Optional Format 1-2-96)