K040703

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DIRUI Industrial Co., Ltd.

510(k) Summary

Prepared: February 13, 2004

Submitter: Dirui Industrial Co. Ltd.

Address: 95 Yunhe Street
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Changchun, 130012, China

Contact Person (U.S. Agent):

Joseph F. Ludford
U.S. Conformity Consultants, Inc.
7560 Lindbergh Drive
Gaithersburg, MD 20879
Tel: 301-417-0220
Fax: 301-417-9069

Trade/Proprietary Name:

URISTIK H Series Reagent Strips For Urinalysis

Common/Usual Name:

Urinalysis Test Strips

Classification Names:

Occult blood test (21 CFR 864.6550) - Class II
Urinary glucose (nonquantitative) test system (21 CFR 862.1340) - Class II
Urinary urobilinogen (nonquantitative) test system (21 CFR 862.1785) - Class I
Urinary bilirubin and its conjugates (nonquantitative) test system (21 CFR 862.1115) - Class I
Ketones (nonquantitative) test system (21 CFR 862.1435) - Class I
Urinary protein or albumin (nonquantitative) test system (21 CFR 862.1645) - Class I
Nitrite (nonquantitative) test system (21 CFR 862.1510) - Class I
Leukocyte peroxidase test (21 CFR 864.7675) - Class I
Urinary pH (nonquantitative) test system (21 CFR 862.1550) - Class I
Ascorbic acid test system (21 CFR 862.1095) - Class I
Specific gravity test (not classified in 21 CFR 862 or 864) - proposed Class I

Note: Occult blood test and urinary glucose test are the subject of this submission.

Legally marketed devices to which we are claiming equivalence:

Bayer Corporation MULTISTIX 10 SG Reagent Strips (K-file not identified)
Behring Diagnostics RAPIGNOST TOTAL SCREEN L Urine Test Strips (K861255)
Boehringer Mannheim CHEMSTRIP 10 with SG Urine Test Strips (K896454)
International Newtech Development Urinalysis Reagent Strips (10 Parameters) (K993850)

Device Description:

URISTIK H Series Reagent Strips For Urinalysis provide qualitative and semi-quantitative tests for ascorbic acid, pH, specific gravity, ketones, blood, protein, nitrite, leukocytes, glucose, bilirubin and urobilinogen in urine. URISTIK H Series Reagent Strips For Urinalysis are firm plastic, dry reagent strips. The reagent areas are dipped into the urine sample and read visually according to a color chart or are read instrumentally with a Dirui H-50, H-100, or H-500 Urine Analyzer. The results are available within one minute. To obtain optimal results, it is necessary to use fresh, well-mixed and uncentrifuged urine.

Intended Use:

URISTIK H Series Reagent Strips For Urinalysis are for professional use in point-of-care (POC) testing such as in hospitals, clinics, and clinical laboratories. The reagent strips are intended for use to assist diagnosis of the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria.

Technological Characteristics:

URISTIK H Series Reagent Strips For Urinalysis include reagent areas for assessing the presence of occult blood and urine glucose. A high concentration of ascorbic acid will effect the test for glucose. Ascorbic acid is reported from 0.6 to 5.0 mmol/L. A glucose reagent is used that measures glucose levels from 5.5 to 55 mmol/L. A blood reagent is used that measures occult blood levels from 10 to 200cells/ μ L.

The test for glucose is based on the glucose-specific glucose oxidase/peroxidase method. Oxidation of glucose forms hydrogen peroxide, which in turn oxidizes a chromogen in the peroxidase reaction to generate green or blue color. The test for blood is based on the peroxidase activity of hemoglobin and myoglobin creating a green color with oxidation of a chromogen. Intact erythrocytes which hemolyze on the test paper will produce a green dot.

Assessment of Performance:

The performance of URISTIK H Series Reagent Strips For Urinalysis was studied in clinical laboratory settings by professional users. The strips were read visually and instrumentally using Dirui H Series Urine Analyzers. The results were compared to results obtained from Bayer MULTISTIX 10 SG Reagent Strips and from laboratory test methods. The studies demonstrated that professional users in centralized and point-of-care (POC) hospital, clinic, and doctor's office settings can obtain valid urinalysis test results.

Conclusion:

URISTIK H Series Reagent Strips For Urinalysis provide 11 reagent tests for urinalysis that are similar in composition and performance to reagent tests currently provided by devices on the U.S. market. URISTIK H Series Reagent Strips For Urinalysis are suitable for use in point-of-care (POC) settings. Dirui studies showed that the URISTIK H Series Reagent Strips For Urinalysis provide test results consistent with laboratory methods and performance comparable to that of Bayer MULTISTIX 10 SG Reagent Strips in POC settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 6 2004

Dirui Industrial Co., Ltd.
c/o Mr. Joseph F. Ludford
President
U.S. Conformity Consultants, Inc.
7560 Lindbergh Drive
Gaithersburg, MD 20879

Re: k040703
Trade/Device Name: URISTIK H Series Reagent Strips
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: JIO, JIL, KQO, JRE, JMA, CEN, LJX, JMT, JIR, JIN, JJQ, CDM
Dated: August 6, 2004
Received: August 23, 2004

Dear Mr. Ludford:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
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: K040703

Device Name: URISTIK H Series Reagent Strips

Indications For Use:

URISTIK H Series Reagent Strips provide qualitative and semi-quantitative tests for ascorbic acid, pH, specific gravity, ketones (acetoacetic acid), blood, protein, nitrite, leukocytes, glucose, bilirubin, and urobilinogen in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and bacteriuria.

Dirui H Series Reagent Strips are for single use in professional near-patient (point-of-care) and centralized laboratory locations. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:

- Kidney function
- Urinary tract infections
- Carbohydrate metabolism (e.g. diabetes mellitus)
- Liver function
- Acid-base balance
- Urine concentration

Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040703