K091472

URITEST 50 and URITEST 500 Urine Analyzer 510(K) Summary

APR 27 2010

Prepared: April 26, 2010

Submitter: ARJ Medical, Inc

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Trade Proprietary Name:

URITEST 50 and URITEST 500 Urine Analyzers

Common/Usual Name:

Automated Urinalysis Analyzer (KQO)

Classification Names:

Automated Urinalysis System (21 CFR 862.2900)
Urinary glucose (non-quantitative) test system (21 CFR 862.1340) – Class II
Urinary bilirubin and its conjugates (non-quantitative) test system (21 CFR 862.1115) – Class I
Ketones (non-quantitative) test system (21 CFR 862.1435) – Class I
Specific Gravity test (not classified in 21 CFR 862 or 864) – proposed Class I
Occult blood test (21 CFR 864.6550) – Class II
Urinary pH (non-quantitative) test system (21 CFR 862.1550) – Class I
Urinary protein or albumin (non-quantitative) test system (21 CFR 862.1645) – Class I
Urinary urobilinogen (non-quantitative) test system (21 CFR 862.1785) – Class I
Nitrite (non-quantitative) test system (21 CFR 862.1510) – Class I
Leukocyte peroxidase test (21 CFR 864.7675) – Class I

Legally marketed devices which we are claiming equivalence:

ARJ Medical Uritest 10 Reagent Strips in conjunction with Bayer Clinitek 50 and 500 - k052719

Device Description:

ARJ Medical Uritest 50 and Uritest 500 urine analyzer is a kind of semi-automatic photoelectronic colorimeter that can be used together with the Uritest 10 Urine Reagent Strips manufactured by ARJ Medical, Inc. Adopting the advanced "super-high luminosity cold light source reflection determination" technology, the "high luminosity cold light source" has two main advantages.

(1) the usable life of a cold light is longer than the normal light source
(2) the temperature of the normal light source will increase during testing, affecting the test result vs the temperature of the cold light source is constant not potentially affecting the result.

It can finish the tests on 10 kinds of biochemical components in urine within 30 seconds, and it also can revise the affects toward the test result which is caused by ambient temperature, ambient light, acid-base scale and abnormally colored sample. The Uritest 50 and Uritest 500 urine analyzers are in vitro-diagnostic devices (IVDD).

Intended Use:

The Uritest 50 and Uritest 500 provide a qualitative result for Nitrites and a semi-quantitative result for Urobilinogen, Bilirubin, Ketone, Blood, Protein, Leucocytes, Glucose, Specific gravity, and pH of urine specimen according to the color change caused by the interaction between the reagent areas and the biochemical components in urine.

Assessment of Performance:

The performance of URITEST 50 and URITEST 500 Urinalysis Analyzers were studied in (3) hospital laboratory settings. Urinalysis strips were read instrumentally using the Uritest 50 and Uritest 500 Urinalysis Analyzer. All samples were natural samples. There were 520 natural negative samples and 381 positive natural urine samples tested at 3 sites combined. Samples were unaltered. For each of the sites the total number of positive and negative samples were: No.1 Clinical Hospital of Jilin University (135 Negative, 110 Positive), China-Japan Friendship Hospital of Jilin University (180 Negative, 140 Positive), The People's Hospital of Jilin Province (205 Negative, 131 Positive). The results were compared to results obtained from Bayer Clinitek 50 and Clinitek 500 Urine Analyzers. The studies demonstrated that professional users in centralized and point-of-care (POC) hospital, clinical and doctor's office setting can obtain valid urinalysis test results.

Conclusion:

The URITEST 50 and URITEST 500 Urinalysis Analyzer provide 10 reagent tests of urinalysis that are similar in composition and performance to reagent tests currently provided by devices on the U.S. market. The URITEST 50 and URITEST 500 Urinalysis Analyzer is suitable for use in point-of-care (POC), hospital, clinical and doctor's office setting. ARJ Medical studies showed that the URITEST 50 and URITEST 500 Urinalysis Analyzer provide test results consistent with laboratory methods and performance comparable to that of the Bayer Clinitek 50 Urine Analyzer and the Bayer Clinitek 500 in point-of-care (POC), hospital, clinical and doctor's office setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

ARJ Medical, Inc.
c/o Mr. Aaron Behar
Vice President
209 State Street
Oldsmar, FL 34677

APR 2 7 2010

Re: k091472
Trade Name: Uritest 50 and Uritest 500 Urine Analyzers
Regulation Number: 21 CFR §864.6550
Regulation Name: Occult blood test.
Regulatory Class: Class II
Product Codes: JIO, JIL, CDM, JJB, JIN, JIR, JMT, LJX, CEN, KSL, KQO
Dated: March 31, 2010
Received: March 31, 2010

Dear Mr. Behar:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, 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: k091472

Device Name: URITEST 50 Urine Analyzer

Indications for Use:

ARJ Medical URITEST 50 urine analyzer is a semi-automated, bench top instrument which is intended for prescription, in vitro diagnostic use with the URITEST 10 Urinalysis Reagent Strips manufactured by ARJ Medical, Inc. This system performs qualitative detection of Nitrites and semi-quantitative detection of Urobilinogen, Bilirubin, Ketone, Blood, Protein, Leukocytes, Glucose, Specific gravity and pH. The instrument uses the accompanying check strip for daily calibration.

ARJ Medical URITEST 50 Urinalysis Analyzer is for use in professional near patient (point-of-care) facilities and centralized laboratory. The analyzer is intended for use in screening at-risk patients to assist diagnosis in the following areas:

Kidney Function
Urinary Tract infections
Carbohydrate metabolism
Liver Function
Acid-Base balance
Urine Concentration

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

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

Carol C Benson

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INDICATIONS FOR USE

510(K) Number: k091472

Device Name: URITEST 500 Urine Analyzer

Indications for Use:

ARJ Medical Uritest 500 urine analyzer is a semi-automated, bench top instrument which is intended for prescription, in vitro diagnostic use with the URITEST 10 Urinalysis Reagent Strips manufactured by ARJ Medical, Inc. This system performs qualitative detection of Nitrites and semi-quantitative detection of Urobilinogen, Bilirubin, Ketone, Blood, Protein, Leukocytes, Glucose, Specific gravity and pH. The instrument uses the accompanying check strip for daily calibration.

ARJ Medical URITEST 500 Urinalysis Analyzer is for use in professional near patient (point-of-care) facilities and centralized laboratory. The analyzer is intended for use in screening at-risk patients to assist diagnosis in the following areas:

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