OCT 1 2 2007

5. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K063295

Submitter's Identification:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-875-8000
Fax: 858-875-8099

Date Prepared: October 31, 2006

Contact Person:

Jinn-nan Lin, Ph.D.
V.P., Regulatory Affairs

Proprietary Name of the Device:

ACON UTI Urinary Tract Infection Test Strips

Common Name:

Urinary Tract Infection Test Strips

Regulation Section and Classification:

21 CFR § 862.1510 Nitrite (Non-Quantitative) Test System
21 CFR § 864.7675 Leukocyte Peroxidase Test

Class I: Urinary Leukocytes, Nitrite

Product Code:

LJX Test, Urine Leukocyte
JMT Nitrite (urinary, non-quant.) test system

Medical Specialty:

Clinical Chemistry

Predicate Device:

Multistix 10 SG Reagent Strips for Urinalysis, K905396
Bayer Corporation, marketed by Bayer Corporation, located at Elkhart, IN 46515, USA.

Device Description:

The ACON UTI Urinary Tract Infection Test Strips for Leukocytes and Nitrite are urine test strips of which Nitrite and Leukocyte reagent pads are affixed onto the plastic strips. The reagent pads react with the urine and provide a visible color reaction. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. The product is packaged with a drying agent in a plastic bottle. The entire reagent strip is disposable when the disposal directions are followed exactly. Laboratory instrumentation is not required. These tests are intended for over-the-counter home use with human urine.

Intended Use:

The ACON UTI Urinary Tract Infection Test Strips is for the qualitative detection of Leukocyte and Nitrite in urine as an aid in the screening of urinary tract infection (UTI). It is intended for over-the-counter home use only.

Tests Principles:

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl)-ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine. The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient.

Substantial Equivalence:

The ACON UTI Urinary Tract Infection Test Strips for Leukocytes and Nitrite are substantially equivalent to the Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396).

Characteristic of the ACON UTI Urinary Tract Infection Test Strips are compared with the Bayer Multistix 10 SG system (K905396) in the following table:

Area of Comparison	ACON UTI Urinary Tract Infection Test Strips	Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396)
Intended Use	For qualitative detection of Leukocyte and Nitrite in urine as an aid in the screening of urinary tract infection (UTI)	For qualitative detection of Leukocyte and Nitrite in urine as an aid in the screening of urinary tract infection (UTI)
Target Population	Lay persons for over-the-counter home use only	Patients of physicians, hospitals, and clinics For professional use in point-of-care urine testing
Intended Specimen	Urine	Same
Material Provided	Plastic strips affixed with several separate reagent areas.	Same
Storage	2 to 30°C	15 to 30°C
Test Time	Varies from 60 Seconds to 2 Minutes .	Same
Nitrite Methodology	This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl)-ethylenediamine to produce a pink color.	Same
Leukocyte Methodology	This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color.	Same

Discussion of Clinical Tests Performed:

The clinical studies were conducted at Beta sites using the ACON UTI Urinary Tract Infection Test Strips (Section 20, page 43 of this submission). Clinical data were presented evaluating clinical accuracy of results. Clinical study results indicate that the inexperienced lay users were able to obtain comparable testing data compared to those obtained by the professionals when using the ACON UTI Urinary Tract Infection Test Strips and the legally marketed Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396).

Conclusion:

The performance characteristics of the ACON UTI Urinary Tract Infection Test Strips were verified by sensitivity study, reproducibility study, interference studies, temperature flex study, read time flex study, and stability studies. Testing results indicate that the ACON UTI Urinary Tract Infection Test Strips are robust and can perform satisfactorily when used according to the "Directions for Use" statement specified in the package insert.

The laboratory testing results and clinical studies demonstrated a substantial equivalency on performance between the ACON UTI Urinary Tract Infection Test Strips and a legally marketed product, Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396), with similar product features and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 12 2007

ACON Laboratories, Inc.
c/o Dr. Jinn-nan Lin
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Re: k063295
Trade/Device Name: ACON UTI Urinary Tract Infection Test Strips
Regulation Number: 21 CFR 862. 1510
Regulation Name: Nitrite (nonquantitative) test system
Regulatory Class: Class I (meets the limitations of exemption in 21 CFR 862.9)
Product Code: LJX, JMT
Dated: September 18, 2007
Received: September 19, 2007

Dear Dr. Lin:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

4. INDICATIONS FOR USE

510(k) Number (if known): K063295

Device Name: ACON™ UTI Urinary Tract Infection Test Strips

Indications for Use:

The ACON UTI Urinary Tract Infection Test Strips are for the qualitative detection of Nitrite and Leukocytes in urine as an aid in the screening of urinary tract infection (UTI). It is intended for over-the-counter home use only.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(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

K063295

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