TECO DIAGNOSTICS

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FEB 17 2011

510(k) SUMMARY

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

The Assigned 510(k) number is k100024

Submitter's Identification:

Teco Diagnostics, Inc.
1268 N. Lakeview Avenue
Anaheim, CA 92807

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Date Prepared: December 18, 2009

Contact Person:

Dr. KC Chen

Proprietary Name of the Device:

Teco Diagnostics UTI Test Strips

Common Name:

Urine Reagent Strips (URS)

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-quantitative) test system

Medical Specialty:

Clinical Chemistry

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Predicate Device:

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

Device Description:

Teco Diagnostics UTI Test Strips provides tests for the qualitative determination of leukocytes and nitrite in urine. The product is a firm plastic strip to which is affixed two separate dry reagent pad areas that is used for urinalysis. The reagent pad areas are bibulous material saturated with chemically active substances. All UTI Test Strips are carefully packaged along with a desiccant in a sealed, foil pouch. The color chart for reading the strips is on the outside of the foil pouch. A package insert is packaged along with the foil pouch into a box. The package insert contains all the necessary product information.

Results of each test are based on the color produced from the reaction of each reagent pad area once the Urine Reagent Strip comes into contact with a urine sample. Each parameter is color coded accordingly as described in the color chart. Results with Teco Diagnostics UTI Test Strips can be obtained in clinically meaningful units directly by comparison with the color chart. The color blocks represent nominal values; actual values will vary around the nominal values.

Intended Use:

The Teco Diagnostics UTI Test Strips are intended 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.

Test Principles:

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to from a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.

Leukocyte: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

Substantial Equivalence:

The Teco Diagnostics UTI Test Strips for Leukocyte and Nitrite are substantially equivalent to the Bayer Multistix 10-SG Reagent Strips for Urinalysis (K905396).

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Comparison of Characteristics with Predicate:

	Teco Diagnostics UTI Test Strips	Bayer Multistix 10 SG Reagent Strips
Intended Use	For the qualitative detection of Nitrite and Leukocyte in urine as an aid in the screening of urinary tract infection (UTI)	For qualitative detection of Glucose, Bilirubin, Ketone, pH, Blood (Occult), Specific Gravity, Protein, Urobilinogen, Leukocyte and Nitrite in urine to assist in diagnosis in kidney function, liver function, metabolic disorders and urinary tract infection.
Intended Users	Lay persons, over-the-counter use	For professional use in point-of-care urine testing
Specimen	Human Urine	Same
Materials Provided	Plastic test strips affixed with reagent pads	Same
Storage	15 - 30°C	Same
Nitrite Test Time	60 seconds	Same
Leukocyte Test Time	2 minutes	Same
Nitrite Parameter Methodology	This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to from a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.	Same
Leukocyte Parameter Methodology	This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.	Same

The devices differ in their intended users. UTI Test Strips are intended for lay users over the counter, whereas Multistix 10 SG is intended for professional use in point-of-care clinical sites. The possible errors associated with lay user testing were investigated in a clinical, comparison study where both lay users and professional users tested the strips on the same sample. The study demonstrated that the strips were able to be read correctly and easily among lay users.

The predicate device, Multistix 10 SG, also tests eight other analytes, including Glucose, Bilirubin, Ketone, pH value, Blood (Occult), Specific Gravity, Protein and Urobilinogen, intended in the assisting the diagnosis in the areas of kidney function, liver function and metabolic disorders. However, these analytes are not used to aid in the diagnosis of urinary tract infection and the safety and effectiveness of Teco Diagnostics' UTI Test Strips are not affected by the drop of these test analytes.

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Summary of Clinical Tests Performed:

The clinical studies were conducted at Point of Care sites and with lay persons using the Teco Diagnostics UTI Test Strips versus Multistix 10 SG. 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 Teco Diagnostics UTI Test Strips and the legally marketed Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396).

Summary of Laboratory Tests Performed:

The Laboratory studies were conducted in house and included sensitivity studies, reproducibility study, interference studies, stress study, and stability studies. The obtained laboratory data indicate that Teco Diagnostics UTI Test Strips run well and met all required performance characteristics.

Conclusion:

The performance characteristics of the Teco Diagnostics UTI Test Strips were verified by sensitivity study, reproducibility study, interference studies, and temperature stress study. Testing results indicate that Teco Diagnostics UTI Test Strips can perform satisfactorily when used according to the "Test Procedure" directions on the package insert.

The laboratory testing results and clinical studies demonstrated a substantial equivalency on performance between the Teco Diagnostics UTI Test Strips and a legally marketed product, Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396), with similar product characteristics and intended use of aid in diagnosis in urinary tract infection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 17 2011

TECO Diagnostics
c/o Dr. KC Chen
1268 North Lakeview Avenue
Anaheim, CA 92807

Re: k100024
Trade Name: TECO Diagnostics UTI Test Strips
Regulation Number: 21 CFR 862.1510
Regulation Name: Nitrite (Non-Quantitative) Test System.
Regulatory Class: Class I: (meets the limitations of exemptions in 21 CFR 862,9(c)(9)
Product Codes: JMT, LJX
Dated: January 12, 2011
Received: February 02, 2011

Dear Dr. Chen:

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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 (If Known): k100024

Device Name: Teco Diagnostics UTI Test Strips

Indications for Use:

The Teco Diagnostics UTI Test Strips are intended 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 _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ✓ (21 CFR 801 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)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k100024