510(k) Summary MAY 2 9 2014

[As required by 21 CFR 807.92(c)]

The assigned 510(k) number is K131600

Submitter Identification:
Teco Diagnostics
1268 N. Lakeview Avenue
Anaheim, CA 92807
Establishment Registration #1832216

Contact Name:
Steve Partono, Ph.D.

Device Proprietary Name:
URS-2GP (Glucose Protein) Urine Strips

Device Common Names:
Urine Reagent Strips (URS)

Regulation Section and Classification:
21 CFR 862.1340 Urinary Glucose (non-quantitative) test system; Class II; Product Code JIL

21 CFR 862.1645 Urinary Protein or albumin (non-quantitative) test system; Class I; Product Code JIR

Review Panel: Clinical Chemistry (75)

Predicate Device:
Urine Reagent Strip-3 Parameter, K940469
Teco Diagnostics, 1268 N. Lakeview Avenue, Anaheim, CA 92807

Intended Use:
The URS-2GP (Glucose Protein) Urine Strips are visually read, semi-quantitative tests for the detection of glucose and protein in urine and are intended for prescription home use. Test results may provide information regarding the status of carbohydrate metabolism and kidney function.

Device Description:
This device consists of glucose and protein reagent pads that are affixed onto firm plastic strips. The reagent pad areas are made of absorbent material saturated with chemically active substance, then dried and affixed to the plastic strip with double-sided adhesive. Each strip is carefully packaged individually along with a desiccant in a sealed, foiled pouch. A package insert is packaged along with the foil pouches into a box. The package insert contains all the necessary product information.

Results of each test is based on the color produced from the reaction of each reagent pad area once the reagent strip comes into contact with a urine sample. Each parameter is color coded accordingly as described in the color chart. Results can be obtained in clinically meaningful units directly by comparison with the color chart on the foil pouch. The color blocks represent different concentrations of urine glucose and urine protein. The entire reagent strip is disposable following federal and local regulations. Laboratory instrumentation is not required.

Test Principles:

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen causing the color to change from blue-green for a "negative" reaction to greenish-brown through brown for a "positive" reaction.

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "negative" reaction to yellow-green and green to blue-green for a "positive" reaction.

Expected Results:

Glucose: Small amounts of glucose are normally excreted by the kidney. Glucose concentrations up to 100 mg/dL are considered normal, but may be abnormal if found consistently.

Protein: Small amounts of protein may be excreted by the normal kidney. Protein concentrations up to 15 mg/dL are considered normal, but may be abnormal if found consistently.

Substantial Equivalence

Based on a comparison of the device features, materials and intended use, this device is substantially equivalent to the following predicate device:

Predicate Device name: URINE REAGENT STRIP-3 PARAMETER
Predicate 510(k) no: K940469

Comparison with Predicate

Table 1: Comparison between New Device and Predicate Device

	URS-2GP (Glucose Protein) Urine Strips	**Predicate**
Intended Use	The URS-2GP (Glucose Protein) Urine Strips are visually read, semi-quantitative tests for the detection of glucose and protein in urine and are intended for prescription home use. Test results may provide information regarding the status of carbohydrate metabolism and kidney function.	The URS-3 provide tests for semi-quantitative determination of glucose, protein and pH in urine.
Human Factor	Lay users, Prescription Home Use	Professional use, POC use
Manufacturer	Teco Diagnostics, Inc.	Same.
Size	108mmx10mm strip, 10mmx10mm pads	80mmx5mm strip, 5mmx5mm pads
Packaging	Individual foil pouch, box of 25 pouches	Bottle of 100 strips
Storage	15-30°C	Same
Test time	Glucose (30s), Protein (1 min)	Glucose (30s), Protein (1 min)
Sample Handling	Random urine (mid-stream).	Random urine (dipped).
Measurement	Visual inspection.	Visual Inspection.
Test Principle	Glucose: This test is based on a double sequential enzyme reaction using glucose oxidase and peroxidase.	Same

	Protein: This test is based on the protein error-of-indicator principle. At a constant pH, tetrabromophenol blue binds with protein and form green color.	Same

The two devices are based on same formulations, with similar performance characteristics. The main differences are 1) the URS-2GP is intended for prescription home use whereas the predicate device is intended for professional use, 2) the new device works using "mid-stream" method whereas the predicate device works using a "dip" method, and 3) the new device is individually packaged in a pouch whereas the predicate device is packaged in a bottle.

Summary of Clinical Tests Performed

A comparison study was performed at three clinical sites by having lay users (n=.162) testing the URS-2GP using mid-stream urine samples, and healthcare professionals testing the same urine sample using a comparator device (URS-3, Teco Diagnostics). The participants were asked to match the test colors with specific color blocks on the color chart and record the glucose and protein values. The data presented here showed that the tests performed by lay users had 92% agreement based on exact match and 100% agreement within one color block.

Summary of Laboratory Tests Performed

The laboratory studies were conducted in house and included sensitivity, precision, interference, stress and stability studies. The obtained laboratory data indicated that the new device had the similar performance characteristics as the predicate device.

Precision

Multiple tests were performed under variable conditions using multiple users, sites and lots of urine controls. The tests were performed using Within Run method (multiple runs within a day) and Run-to-Run method (multiple runs on multiple days). The results showed that the device has 96% agreement based on exact match and 100% agreement within one color block).

Sensitivity

The sensitivity range for each color block was determined by performing multiple tests at various concentrations of analyte near each color block. Sensitivity range of a color block is determined by the concentrations where 95% of the test results yielded correct results.

Specificity

The device was tested with compounds similar to glucose and protein to determine if it has cross-reactivity. The glucose analogues tested included galactose, fructose, lactose, and sucrose, while the protein analogues tested included globulin, hemoglobin, Bence Jones, and mucoprotein. The glucose test did not react with any of the glucose analogues at concentrations up to 500 mg/dL. The protein test was specific for albumin, but also had some reactivity to globulin and Bence-Jones protein at concentrations higher than 100 mg/dL.

Interference

The device was tested in the presence of potential interfering compounds which may affect the urine glucose and urine protein tests. A substance is considered to cause interference if the addition of the substance causes the test reading to be off by at least one color block. The results showed that ascorbic acid (50 mg/dL) and MESNA (25 mg/dL) had interference effect on the urine glucose test. MESNA (25 mg/dL) also had interference effect on the urine protein test, while ascorbic acid up to 500 mg/dL had no effect on the urine protein test. Hemoglobin concentration of 100 mg/dL or above causes atypical color of urine which renders the urine glucose and urine protein tests invalid.

Conclusions

The data presented demonstrate that URS-2GP (Glucose Protein) Urine Strip is substantially equivalent to URS-3. The two devices are based on same formulations, with similar performance characteristics. The clinical results also demonstrate a high correlation between URS-2GP and the URS-3 even though the new device was tested by lay users while the predicate device was tested by professional users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2014

TECO DIAGNOSTICS
STEVE PARTONO
DIRECTOR OF RESEARCH AND DEVELOPMENT
1268 NORTH LAKEVIEW AVE.
ANAHEIM CA 92807

Re: K131600
Trade/Device Name: URS-2GP (Glucose Protein) Urine Strips
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: II
Product Code: JIL, JIR
Dated: April 30, 2014
Received: April 30, 2014

Dear Dr. Steve Partono:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131600

Device Name
URS-2GP (Glucose Protein) Urine Strips

Indications for Use *(Describe)*
The URS-2GP (Glucose Protein) Urine Strips are visually read, semi-quantitative tests for the detection of glucose and protein in urine and are intended for prescription home use. Test results may provide information regarding the status of carbohydrate metabolism and kidney function.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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