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

September 21, 2017

TECO DIAGNOSTICS
LING KOH
R&D ENGINEER
1268 N LAKEVIEW AVE
ANAHEIM CA 92807

Re: K170118
Trade/Device Name: Scanostics UTI Check Application Test System
Regulation Number: 21 CFR 862.1510
Regulation Name: Nitrite (nonquantitative) test system
Regulatory Class: I, meets the limitations of exemptions 21 CFR 862.9(c)(9)
Product Code: JMT, LJX, KQO
Dated: August 9, 2017
Received: August 16, 2017

Dear Ling Koh:

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" (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 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,

Kellie B. Kelm -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k170118

Device Name
Scanostics UTI Check Application test system

Indications for Use *(Describe)*
The Scanostics UTI Check Application test system consists of the Scanostics UTI Check Application and the URS-2L (UTI) Urine Test Strips. The test system is intended for the qualitative detection of nitrite and leukocytes in urine as an aid in the screening of urinary tract infections (UTI). It is intended for over-the-counter home use only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Teco Diagnostics
1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiagnostics.com

Section 5 - 510(k) Summary

This Summary of 510(k) Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Owner's Name
Teco Diagnostics

Address and Contact Information:
1268 N Lakeview Ave
Anaheim, CA
92807

Contact:
Ling Koh

Date Prepared:
9 August 2017

Teco Diagnostics
1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiagnostics.com

A. 510(k) Number: k170118

B. Analytes:
Urinary leukocytes, nitrites

C. Type of Test:
Semi-quantitative colorimetric test strips

D. Applicant:
Teco Diagnostics

E. Trade Name:
Teco Diagnostics Scanostics UTI Check Application Test System

F. Common Name:
Urine Reagent Strips (URS)

G. Regulatory Information:

1. Regulation Classification Section:
   Class I: 21 CFR 864.7675 (meets the limitations of exemptions per 21 CFR 864.9 (c)(9))- Leukocyte peroxidase test,)
   Class I: 21 CFR 862.1510 (meets the limitations of exemptions per 21 CFR 862.9 (c)(9))- Nitrite (non-quantitative) test system
   Class I: 21 CFR 862.2900 – Automated urinalysis system
2. Product Code:
   LJX - Leukocyte peroxidase test
   JMT - Nitrite (nonquantitative) test system)
   KQO
3. Panel:
   Hematology for LJX
   Clinical Chemistry for JMT

H. Intended Use:
The Scanostics UTI Check Application test system consists of the Scanostics UTI Check Application and the URS-2L (UTI) Urine Test Strips. The test system is 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.

I. Device Description:

Teco Diagnostics
1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiagnostics.com

The Scanostics UTI Check Application test system consists of the Scanostics UTI Check Application and the URS-2L (UTI) Urine Test Strips. The Scanostics UTI Check Application measures the colour developed in two reaction zones (leukocytes and nitrite pads) on the UTI test strip following application of a urine sample. The developed colors are then compared to calibration colours located on the Scanostics backing material and the result for each pad is determined based on the minimum colour distance between the developed colours and calibration colours.

The URS-2L UTI Test Strip comprises of two reagent pads areas, which are absorbent material saturated with chemically active substances, then dried and affixed to the plastic strip with double-sided adhesive.

The backing card comprises of thirty-two (32) calibration colour blocks and three (3) black and white alignment squares printed onto a rigid card stock and die cut to provide a groove for the strip (preventing strip misalignment). The use of the backing card is primarily to compensate for different lighting environments as it allows the calibration colours and the test strip to be subjected to the same conditions as the reagent pads for comparison – this would not be possible if the calibration colours were stored within the application itself.

The representative platform for the test system is the iPhone 6 with iOS 9. The application has been proven to be compatible on the iPhone 6S (iOS 9) and iPod touch (8th gen with iOS 8 and iOS 9). The application's core technology is based on four (4) patents held by Teco Diagnostics (US 8655009, 8877140, 8911679 and 8506901).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Clinistrip 10SGL
2. Predicate K number(s)
   k970250
3. Compare with predicate:
   Table 5.1 Scanostics UTI Check Application vs Clinistrip

Similarities		
Item	**Scanostics UTI Check**	**Clinistrip**
Intended use	Over the counter, in vitro diagnostic only	Point-of-care, in vitro diagnostic use only
Testing parameters	Nitrite and leukocytes	10 parameters including nitrite and leukocytes

Teco Diagnostics
1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiagnostics.com

Intended specimen	Urine (midstream)	Urine (collected)
Test strip	Plastic strips affixed with reagent pads	Same
Nitrite methodology	This test relies on the conversion of nitrate to nitrite by the action of *p*-arsanilic acid to form a diazonium compound in an acid medium. This compound in turn couples with 1, 2, 3, 4 - tetrahydrobenzo(h) quinolin to produce a pink color.	Same
Leukocyte methodology	This test is based on the hydrolysis of an indoxyl ester derivative through the action of leukocyte esterase. The liberated indoxyl ester reacts with a diazonium salt to produce a colored compound (pink to purple).	Same

Differences		
Item	**Scanostics**	**Clinistrip**
Imaging system	Smartphone camera	Eye
Accessory items	Smartphone, backing card	None
Calibration method	Calibration colours provided on backing card	Strip compared to colour chart on bottle
Operating interface	Touch screen	None
Data collection/storage	Application has the capability to store both the results and the image captured. Users may retrieve stored results with a password and share results via email.	None
Dimensions	Test strip: 10 mm x 80 mm Backing card: 50 mm x 80 mm Smartphone (depending on model): 115 mm x 59 mm x 7 mm and larger	Test strip: 5 mm x 110 mm
Weight	Test strip: 0.8 g Backing card: 2.2 g	Test strip: 0.32g

Teco Diagnostics
1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
Fax: (714) 463-1169
www.tecodiagnostics.com

	Smartphone: 110 g and up	
Power	Smartphone powered by rechargeable lithium ion battery	None

The candidate device (application and test strips) uses the same chemical formulation for leukocyte and nitrite reagent pads as the predicate. The main difference between the investigational and predicate device is the inclusion of the smartphone accessory and the backing card.

K. Test Principle:

Leukocytes: This test is based on the hydrolysis of an indoxyl ester derivative through the action of leukocyte esterase. The liberated indoxyl ester reacts with a diazonium salt to produce a colored compound (pink to purple).

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

L. Clinical Performance Characteristics:

The lay user studies were performed at three sites using the Scanostics UTI Check Application test system and the Clinistrip (URS-10) strips. Lay user data was presented to evaluate the accuracy of results in the hands of users and to ensure that the intended users were able to understand and implement smartphone technology.

Results indicate that the intended users were able to obtain comparable testing data when using the Scanostics UTI Check Application as a trained HCP using the Clinistrip (URS-10).

M. Non-clinical studies:

The performance characteristics of the Scanostics UTI Check Application test system were verified by method comparison, precision, detection limit, interference, specificity, shelf life and stress studies as well as several flex studies. Testing results indicate that the Scanostics UTI Check application test system performs satisfactorily when used appropriately.

N. Conclusion:

The study results demonstrate a substantial equivalency on performance between the Scanostics UTI Check application test system and the predicate device, Clinistrip (URS-10) test strips.