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

July 6, 2017

ACON LABORATORIES, INC.
QIYI XIE, SR. STAFF CLINICAL/REGULATORY
10125 MESA RIM ROAD
SAN DIEGO, CA 92121

Re: K170587
Trade/Device Name: On Call Ketone Reagent Strips for Urinalysis
Healthy Me Ketone Reagent Strips for Urinalysis
Regulation Number: 21 CFR 862.1435
Regulation Name: Ketones (nonquantitative) test system
Regulatory Class: Class I, meets the limitations of exemption per CFR 862.9(c)(9)
Product Code: JIN
Dated: May 12, 2017
Received: May 15, 2017

Dear Qiyi Xie:

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 Part 801 and Part 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 regulation (21 CFR Part 801 and Part 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,

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k170587

Device Name
Healthy Me™ Ketone Reagent Strips for Urinalysis

Indications for Use *(Describe)*
The Healthy Me™ Ketone Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative detection of Ketone (Acetoacetic acid) in urine. The identification of ketones is used in the diagnosis of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets.

The Healthy Me™ Ketone Reagent strips are intended for Over the Counter use by lay people with Diabetes and/or people on low carb diets at home to check for the ketones in urine. This product is not intended for the management of diabetes.

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.**

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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)*
k170587

Device Name
On Call Ketone Reagent Strips for Urinalysis

Indications for Use *(Describe)*
The On Call Ketone Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative detection of Ketone (Acetoacetic acid) in urine. The identification of ketones is used in the diagnosis of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets.

The On Call Ketone Reagent strips are intended for Over the Counter use by lay people with Diabetes and/or people on low carb diets at home to check for the ketones in urine. This product is not intended for the management of diabetes.

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)

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**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: k170587

**Submitter's Identification:**

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121

Tel.: 858-875-8011
Fax: 858-875-8099

Date Prepared: May, 12th 2017

**Contact Person:**
Qiyi Xie MD, MPH
Sr. Staff Clinical & Regulatory Affairs

**Proprietary Name of the Device**:

On Call® Ketone Reagent Strips for Urinalysis
Healthy Me™ Ketone Reagent Strips for Urinalysis

**Common Name**:

Urinalysis Reagent Strips

**Regulation Section and Classification:**

Regulatory Section: 21 CFR § 862.1435

Classification: Class I meets limitations of exemption per 21 CFR 862.9 (c) (9)

**Product Code:**

JIN Ketones (urinary, non-quant.) test system

**Panel:**

75 Clinical Chemistry

**Predicate Device:**

Predicate 510(k) number & device name:

k801270 - Bayer Ketostix reagent strips, Urine Dipstick or tablet analysis, non- automated

**Device Description:**

On Call® & Healthy Me™ Ketone Reagent Strips for Urinalysis consists of a Plastic Strip to which a regent pad is affixed. The reagent pad reacts with the urine and provides a visible color reaction. On Call® & Healthy Me™ Ketone Reagent Strips for Urinalysis are packaged along with a drying agent in a Canister bottle. Each strip is stable and ready to use upon removal from the Canister. The entire reagent strip is disposable. Results are obtained by direct comparison to the test strip with a color blocks printed on the bottle label. Accurate timing is essential to provide optimal results. No calculations or laboratory instruments are needed.

**Intended Use:**

1. Intended use:

The On Call® & Healthy Me™ Ketone Reagent Strips for Urinalysis are intended for the qualitative and semi-quantitative detection of Ketone (Acetoacetic acid) in urine. The identification of ketones is used in the diagnosis of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets.

The On Call® & Healthy Me™ Ketone Reagent strips are intended for Over the Counter use by lay people with Diabetes and/or people on low carb diets at home to check for the ketones in urine. This product is not intended for the management of diabetes.

2. Special condition for use statement(s):

This submission is for an over-the-counter version of a previously cleared professional device for urine ketones (k061559-ACON Urinalysis Reagent Strips). Lay users can perform the test using the midstream technique or the dip and read technique.

3. Special instrument Requirements:
Not Applicable

**Tests Principles:**

This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

**Substantial Equivalence:**

The On Call® & Healthy Me™ Ketone Reagent Strips for Urinalysis are substantially equivalent to the Bayer Ketostix reagent strips.

**Characteristic of the On Call® Ketone Reagent Strips for Urinalysis are compared with the Bayer Ketostix reagent strips in the following table:**

| Area of Comparison | On Call® & Healthy Me™ Ketone Reagent Strips | Bayer Ketostix reagent strips k801270 |
|---|---|---|
| **Reagent for Ketone (Acetoacetic acid)** | Sodium nitroprusside Buffer | Same |
| **Intended Specimen** | Urine | Same |
| **Material Provided** | Plastic strip affixed with a reagent pad. | Same |
| **Ketone Methodology** | Based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. | Same |
| **Intended Use** | For the qualitative and semi-quantitative detection of ketone in urine. | Same |
| **Intended Use population** | For Over the Counter use by lay people | Professionals and for Over the Counter use by lay people |
| **Time Required to Read Strips** | 15 to 120 seconds | 15 seconds |
| **Storage** | 2 to 30ºC (36-86 ºF) Do Not Store in refrigerator or freezer. Do Not Store in Direct Sunlight | 15 to 30ºC (59-86 ºF) Do Not Store in refrigerator or freezer. Do Not Store in Direct Sunlight |

**Standard/Guidance Document Referenced (if applicable):**

CLSI GP16 A3

**Performance Characteristics (if/when applicable):**

I) Analytical performance: The performance of Ketone reagent strips has been evaluated and present in 510k- k061559-ACON Urinalysis Reagent Strips.

II) Discussion of Clinical Tests Performed:

i) Method comparison with predicate device:

Approximately over 400 participants volunteered in the study participants were recruited.

**Results:**

1. Results of ACON Ketone by Layperson vs Bayer Ketostix by Technician at 3 Sites with the solution concentrations same as color blocks

| | Color blocks | Results Bayer Ketostix by Technician at 3 Sites | | | | | | Total |
|---|---|---|---|---|---|---|---|---|
| | | Neg | 5 | 15 | 40 | 80 | 160 | |
| Result of Acon Ketone strip by layperson | Neg | 60 | 0 | 0 | 0 | 0 | 0 | 60 |
| | 5 | 0 | 57 | 0 | 0 | 0 | 0 | 57 |
| | 15 | 0 | 0 | 55 | 0 | 0 | 0 | 55 |
| | 40 | 0 | 0 | 1 | 52 | 0 | 0 | 53 |
| | 80 | 0 | 0 | 0 | 0 | 60 | 0 | 60 |
| | 160 | 0 | 0 | 0 | 0 | 1 | 61 | 62 |
| | Total | 60 | 57 | 56 | 52 | 61 | 61 | 347 |
| Same block agreement | | 60/60 | 57/57 | 55/56 | 52/52 | 60/61 | 61/61 | 99.4% |
| Agreement within +/- one block | | 60/60 | 57/57 | 56/56 | 52/52 | 61/61 | 61/61 | 100.0% |

2. Participants' Midstream Urine with ACON Ketone Reagent Strips by Layperson vs Urine Collected in Cup with Bayer Ketostix by Technician at 2 sites

| Color block | | Result (mg/dL) of Bayer Ketostix by Technician | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Neg | 5 mg/dL (+/-) | 15 mg/dL (+) | 40 mg/dL (++) | 80 mg/dL (+++) | 160 mg/dL (+++) | Total |
| Results (mg/dL) of ACON Ketone Reagent Strip by Layperson | Neg | 42 | 0 | 0 | 0 | 0 | 0 | 42 |
| | 5 mg/dL (+/-) | 0 | 21 | 0 | 0 | 0 | 0 | 21 |
| | 15 mg/dL (+) | 0 | 0 | 6 | 0 | 0 | 0 | 6 |
| | 40 mg/dL (++) | 0 | 0 | 0 | 2 | 0 | 0 | 2 |
| | 80 mg/dL (+++) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 160 mg/dL (++++) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Total | 42 | 21 | 6 | 2 | 0 | 0 | 71 |
| Same block agreement | | 100% | | | | | | |
| ±1 block agreement | | 100% | | | | | | |

III) Clinical Studies:

i) Clinical sensitivity:
Not Applicable

ii) Clinical specificity:
Not Applicable

IV) Expected values/Reference range:

Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate situations, ketones appear in the urine in excessively large amounts before serum ketones are elevated.

**Conclusion:**

The Method comparison study with predicate indicates that the intended user (layperson) can follow the product instruction, perform the test and obtained comparable results vs. the predicate device. Layperson also can obtain the comparable results vs the results obtained by technician. The above mentioned results demonstrate that the On Call and Healthy Me Ketone reagent strips for urinalysis are substantially equivalent to legally marketed predicate device currently sold on the U.S. market.