January 10, 2025

Safecare Biotech (Hangzhou) Co., Ltd.
Selina Zhang
Manager
18 Haishu Road, Yuhang District
Hangzhou, 311121
China

Re: K242767
Trade/Device Name: Safecare Urinary Tract Infection Test
Regulation Number: 21 CFR 862.1510
Regulation Name: Nitrite (Nonquantitative) Test System
Regulatory Class: Class I (meets the limitations of exemptions in 862.9(c)(9))
Product Code: JMT, LJX
Dated: December 9, 2024
Received: December 9, 2024

Dear Selina Zhang:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Division Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242767

Device Name

Safecare Urinary Tract Infection Test

Indications for Use *(Describe)*

The Safecare Urinary Tract Infection Test is for the qualitative detection of Leukocytes (LEU,white blood cells) and nitrite (NIT) in urine as an aid in the screening of a Urinary Tract infection (UTI). It is intended for over-the-counter home use.

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."

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Safecare Biotech (Hangzhou) Co., Ltd.
Applicant Address	18 Haishu Road, Yuhang District Hangzhou, China Hangzhou 311121 China
Applicant Contact Telephone	086-57181389219
Applicant Contact	Ms. Selina Zhang
Applicant Contact Email	Dylan.wu921@gmail.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	Safecare Urinary Tract Infection Test
Common Name	Leukocyte peroxidase test
Classification Name	Nitrite (nonquantitative) test system
Regulation Number	862.1510
Product Code(s)	JMT, LJX

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231045	Healgen URS Test Strips	LJX

Device Description Summary 21 CFR 807.92(a)(4)

Urinary Tract Infection Test is in vitro diagnostic test device for qualitative detection of leukocyte and nitrite in urine. The device is composed of two-color pads aligned on a strip. One pad is employed for testing leukocyte and the other for nitrite by visually reading the color change of the pad and comparing with the corresponding blocks on a color chart.
The Safecare Urinary Tract Infection Test are for the qualitative detection of Leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a Urinary Tract infection (UTI). It is intended for over-the-counter home use only.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Safecare Urinary Tract Infection Test is for the qualitative detection of Leukocytes (LEU,white blood cells) and nitrite (NIT) in urine as an aid in the screening of a Urinary Tract infection (UTI). It is intended for over-the-counter home use.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The device has the same indications for use in comparison to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The indications for use of proposed device is the same as predicate device K231045,i.e. For the detection of nitrite and leukocytes in urine.
The Nitrite test methodology of proposed device is the same as predicate device K231045, i.e. By conversion of nitrate to nitrite using the action of parsanilic acid to form a diazonium compound in an acid medium. This compound then couples with 1, 2, 3, 4 -

tetrahydrobenzo(h) quinoline to produce a pink color.
The Leukocyte test methodology of proposed device is the same as predicate device K231045, i.e. By 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).
The Specimen type of proposed device is the same as predicate device K231045, i.e. Human urine.
The Testing parameters of proposed device is the same as predicate device K231045, i.e. Nitrite and leukocytes.
The Conditions for Use of proposed device is the same as predicate device K231045, i.e. Over-the-Counter
The Test Read Time of proposed device is the same as predicate device K231045, i.e. 2 minutes for both nitrite and leukocytes.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

1.Precision and Reproducibility
The precision study on the Safecare Urinary Tract Infection Test was performed at three (3) clinical sites with two (2) operators at each site. The evaluation included three (3) replicate assays over five (5) days with the midstream method. A total of forty-five (45) assays results on each of eight levels of control were obtained. All sample concentrations were masked. Three lots of the device were used with each level of control.
2.Analytical Specificity/Interference
Potentially interfering substances were added to negative urine or urine with different leukocyte and nitrite concentrations. These samples were tested with three lots of the Safecare Urinary Tract Infection Test by three different operators (one operator per lot). The following substances (Albumin, Ammonium Chloride, Ascorbic Acid, Bilirubin, Ciprofloxacin, Creatinine, Fructose, Galactose, Glucose, Glycine, Hemoglobin, Lactose, Oxalic Acid, Phenazopyridine, Phenolphthalein, Potassium Chloride, Riboflavin, Sodium Nitrate, Sodium Phosphate, Sulfamethoxazole, Theophylline, Urea) showed no interference with the tests at the specified concentrations.
High glucose levels (≥1000 mg/dL) and high ascorbic acid (≥150 mg/dL) may decrease leukocyte readings. High ascorbic acid (≥150 mg/dL) may cause a false negative nitrite reading.
To investigate the effect of urine specific gravity and urine pH, urine samples with specific gravity ranging from 1.000 to 1.035 and urine samples with pH ranging from pH of 5 to 9 were tested at different leukocyte and nitrite concentrations. The test results show that pH >8.0 may cause false positive leukocyte readings, and specific gravity ≥1.035 may cause false negative leukocyte readings. There is no effect of both pH and specific gravity on nitrite testing.
To address the observed interference, the labeling indicates that dehydration (high specific gravity), high glucose, and high vitamin C (ascorbic acid) may interfere with results. The labeling also describes that urine with abnormal color (e.g., bright yellow or green) should not be tested.
Sample Carryover
A sample carryover study was performed. Three (3) lots of test strips were used for testing. The study was performed by placing the moistened reagent strip (both by immersing it in the sample and simulating urination) vertically, either upwards or downwards, and hold for 10 seconds to allow the sample fluid to flow between the reaction pads on the strip (i.e., run-over for the leukocyte pad to the nitrite pad with the sample with high concentration of leukocyte and negative/normal concentration of nitrite and runover for the nitrite to the leukocyte pad with the sample with high concentration of nitrite and negative/normal concentration of leukocyte). Testing was also repeated in the other direction. The study demonstrated that carryover (run-over) does not impact the test results.

3.Assay Reportable Range
The results of the analytical studies support the following measurement ranges:
Leukocytes: qualitative: Negative, Trace, +, ++, +++; semi-quantitative: Negative, 0.0018, 0.0084,0.0015, 0.060(mg/mL)
Nitrite: qualitative: Negative, Positive

4. Traceability, Stability, Expected Values
Traceability
The nitrite test is traceable to NIST SRM 8040 and the leukocyte pad is traceable to a commercially available solution.
Stability
The sponsor provided information to support that the device is stable for 24 months when stored at 4-30 ℃ based on real-time stability studies.
The sponsor instructs the user to use the test strip immediately after the foil pouch is opened based on the results of the open-pouch stability study that demonstrated an open-pouch stability of 1 hour
5. Assay Cut-off
A sensitivity study was performed to evaluate the lower limits of detection for each analyte on the URS Test Strips. Urine samples were spiked to known concentrations of each analyte. These samples were then diluted to the lowest positive concentrations that are indicated on the color chart. Each sample was tested in 30 replicates with three (3) device lots by three (3) different operators. The sponsor defined the LOD as the concentration of analyte that produces positive URS Test Strip results approximately 95% of the time. The results support the claim that the sensitivity of the leukocyte test is 0.0018mg/mL and the sensitivity of the nitrite test is 0.05 mg/dL. The sponsor provided studies to support the recommended urination time (1-2 seconds) and the recommended reading time (2 minutes).

6.Comparison Studies:

Lay user Study

Three (3) sites were selected to perform the lay-user studies. One hundred fifty-four (154) lay users with UTI symptoms were recruited to test their own urine sample using the Urinary Tract Infection Test. Laypersons performed one test with the Urinary Tract Infection Test according to the product insert and then collected a sample of their urine for comparison testing by healthcare professionals using the predicate device. The results obtained by the lay users using the Urinary Tract Infection Test compared to the results obtained by the healthcare professionals using the predicate device are summarized below.

Results from 154 subjects testing their own urine samples using the midstream collection method for leukocytes: the % Agreement (Exact Match) of each grad are: 90.00% (+++), 90.91% (++), 91.18% (+), 88.89% (Trace) and 100.0% (-), and for % Agreement (+/- Color Block), all grads are 100%.

Results from 154 subjects testing their own urine samples using the midstream collection method for nitrite: the %Agreement (Exact Match) are both 100% for positive (60 cases) and negative (94 cases).

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

Based on the test principle and performance characteristics of the device including precision/reproducibility, Analytical specificity/ Interference, Sample Carryover, assay cut-off and lay-user studies of the devices, it's concluded that Safecare Urinary Tract Infection Test is substantially equivalent to the predicate.