February 20, 2026

QSTag Inc.
JunHyuck Jang
RA Manager
2104, Building M, 32 Songdo Science-ro, Yeonsu-gu
Incheon, 21984
Republic of Korea

Re: K252619
Trade/Device Name: QSCHECK UISACR
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY, JIR, KQO
Dated: January 16, 2026
Received: January 20, 2026

Dear JunHyuck Jang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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 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.

510(k) Number *(if known)*
k252619

Device Name
QSCHECK UISACR

Indications for Use *(Describe)*
QSCHECK UISACR is intended for the in vitro semi-quantitative measurement of the following parameters: microalbumin and creatinine in urine specimens and for Albumin/Creatinine ratio (ACR) calculated using those values. The results may be used in conjunction with clinical evaluation as an aid in the assessment for kidney function. The system is intended for prescription use only, in clinical laboratory settings.

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."

1. Contact Details

Applicant Name	QSTag Inc.
Applicant Address	2104, Building M, 32 Songdo Science-ro, Yeonsu-gu Incheon 21984 Korea, South
Applicant Contact Telephone	+82-32-859-3838
Applicant Contact	Mr. Junhyuck Jang
Applicant Contact Email	junhyuck@qstag.com
Date Prepared	February 20, 2026

2. Device name

510(k) number	K252619
Device Trade Name	QSCHECK UISACR
Common Name	Creatinine test system
Classification Name	Enzymatic Method, Creatinine Indicator method, protein or albumin (urinary, non-quant.) Automated urinalysis system
Regulation Number	862.1225 862.1645 862.2900
Product Code(s)	JFY JIR KQO

3. Legally Marketed Predicate Devices

510(k) number	K182384
Trade name	ACR LAB Urine Analysis Test System
Product code	JFY, JIR, KQO
Submitter	Healthy.io Ltd

4. Device Description Summary

QSCHECK UISACR consists of urine test strips and a smartphone application. In the test strips, the color of the reagent pad that contains enzymes and chemicals is changed according to the concentration of each biomarker in the urine. After the reaction on the strips, the degree of color change is photographed and analyzed by a smartphone application, QSCHECK-app, that runs on both Apple iPhone 14 (iOS v26) and Samsung Galaxy S23 (Android v16).

The software of the QSCHECK-app. recognizes the location of the reagent pad through the QR code on the urine test strip and checks the degree of color development using RGB color codes. The RGB color codes are converted to Hue (H), Saturation (S), Value (V) color model, which is a method of expressing color or arranging colors according to this method. The results are displayed by matching colorimetric tables for each section that were previously classified according to HSV.

5. Intended Use/ Indication for Use

QSCHECK UISACR is intended for the in vitro semi-quantitative measurement of the following parameters: microalbumin and creatinine in urine specimens and for Albumin/Creatinine ratio (ACR) calculated using those values. The results may be used in conjunction with clinical evaluation as an aid in the assessment for kidney function. The system is intended for prescription use only, in clinical laboratory settings.

6. Indications for Use Comparison

Item	**Subject Device** QSTag, Inc. / QSCHECK UISACR	**Predicate Device** Healthy.io, Ltd. / ACR | LAB Urine Analysis Test System (k182384)
Intended Use	The in vitro semi-quantitative measurement of the following parameters: microalbumin and creatinine in urine specimens and for Albumin/Creatinine ratio (ACR) calculated using those values.	Same
Intended Users	For prescription use only	Same

7. Technological Comparison

Item	**Subject Device** QSTag, Inc. / QSCHECK UISACR	**Predicate Device** Healthy.io, Ltd. / ACR | LAB Urine Analysis Test System (k182384)
Measurands	Microalbumin, Creatinine	Same
Measurement Range	Microalbumin: 1 – 15 mg/dL Creatine: 10 – 300 mg/dL	Same

Item	Subject Device QSTag, Inc. / QSCHECK UISACR		Predicate Device Healthy.io, Ltd. / ACR | LAB Urine Analysis Test System (k182384)
Measurement block	Microalbumin: 1, 3, 8, 15 mg/dL Creatinine: 10, 50, 100, 200, 300 mg/dL		Same
Specimen	Human Urine		Same
Sample application	Dipping		Same
Dipping time	1 second		Same
Reaction time	60 seconds		Same
Test Principle	Microalbumin:	Microalbumin test is based on dye binding using sulfonephthalein dye. At a constant pH, albumin binds with sulfonephthalein dye to develop a color ranging from pale green to aqua blue.	Same
	Creatinine	Creatinine test is based on the reaction of creatinine with a dye-metal complex. At an alkaline condition, creatinine reacts with a dye-metal complex to form a purplish brown color complex	Same
Instrument	Galaxy S23, iPhone 14		iPhone 7
Operating system	Android v.16 iOS v.26		iOS v.12

8. Non-Clinical and/or Clinical Tests Summary & Conclusions

Precision

Repeatability study was done in accordance with CLSI EP05-A3. The study was conducted by one (1) operator at one (1) test site using three (3) urine samples representing albumin concentrations of 1, 8, and 15 mg/dL; creatinine concentrations of 10, 100, and 200 mg/dL; and corresponding ACR categories of normal, abnormal, and very abnormal. Two (2) types of smartphone devices, Apple iPhone 14 running iOS v26 and Samsung Galaxy S23 running Android v16, and one (1) test strip lot were used.

<Within-run precision>
The experiment was conducted once a day with twenty (20) replicates for each test sample.
<Between-run precision>
The experiment was conducted over a single day, with two (2) runs. Ten (10) replicates per test sample was tested per run.

<Between-day precision>
The experiment was conducted over five (5) days. There was one run per testing day, with four (4) replicates per test sample. Total twenty (20) test results were obtained for each analyte, concentration and smartphone.
The match rates were found all 100%.

The reproducibility testing was conducted at three (3) test sites, with one (1) operator at each site. Three (3) urine samples representing albumin concentrations of 1, 8, and 15 mg/dL; creatinine concentrations of 10, 100, and 200 mg/dL; and corresponding ACR categories of normal, abnormal, and very abnormal were used. Each operator used one (1) Apple iPhone 14(iOS v26) and one (1) Samsung Galaxy S23(Android v16), along with three (3) test strip lots. One run per day was performed with five (5) replicates per run over five (5) days.
The match rates are found all 100% for all tests during the study.

Analytical Sensitivity (Detection Limit)

A sensitivity study was performed to evaluate the lower limits of detection for each the analytes measuring block on the QSCHECK UISACR utilizing the QSCHECK-app. The samples were spiked and diluted with negative urine to produce different levels of albumin and creatinine. For a total of three (3) test strip lots, 10 replicate results were obtained at each concentration level for each lot, using two (2) types of smartphone devices, Apple iPhone 14(iOS v26) and Samsung Galaxy S23(Android v16). The cut-offs for each measuring block are defined as the lowest concentrations of analyte tested at which over 50% of the results are positive for each measuring block.

Analytical Specificity (Interference)

Testing of potential interfering substances with the QSCHECK UISACR was designed and executed in accordance with guidance provided by CLSI EP07 – Interference Testing in Clinical Chemistry – Third Edition; and EP37 - Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition.
Urine samples for albumin (1 mg/dL, 8 mg/dL, 15 mg/dL) or creatinine (200 mg/dL, 100 mg/dL, 10 mg/dL) were spiked with each potentially interfering substance at each concentration or not spiked (control). Each sample was tested with one (1) lot of test strip with ten (10) replicates using one (1) Apple iPhone 14(iOS v26) and one (1) Samsung Galaxy S23(Android v16) smartphone. The match rate of the test samples with interfering substance were compared to the match rate of the control samples. If the match rate of the interferents is equal to or higher than that of the control samples, it is defined as having no interference. When interference was observed, further testing was conducted to identify the highest concentration at which interference was not observed.

Linearity/assay reportable range

Testing was conducted with urine samples spiked to 5 levels of creatinine (expected outputs of 10, 50, 100, 200, and 300 mg/dL), 4 levels of albumin (expected outputs of 1, 3, 8, and 15 mg/dL), and 3 levels of ACR (expected outputs of Normal, Abnormal, and Very abnormal). The testing was conducted by three (3) operators at one (1) test site, each using one (1) iPhone 14(iOS v26) and one (1) Galaxy S23(Android v16) smartphone, and three (3) test strip lots, with each operator testing each urine sample in 10 replicates per lot.
The match rates are found all 100% for all tests during the study.

Stability

Stability testing was conducted on three batches produced according to EN ISO 13485:2016. The effect of storage temperature was evaluated by setting the strip storage temperature to 2°C (±2°C) and 30°C (±2°C), representing the lowest and highest temperatures, respectively. For each batch and temperature at each time point, the measurement was repeated three times. Through the study, it was confirmed that the performance was maintained for up to 20 months at a storage temperature of 2°C and 30°C.

Method Comparison

A total of 300 microalbuminuria patient specimens have been prepared across the three (3) clinical sites though the IRB process from each site. The study was conducted over three (3) days using two (2) test methods, by one (1) operator at three (3) different sites, using two smartphone models, Apple iPhone 14 running iOS v26 and Samsung Galaxy S23 running Android v16. The results from the QSCHECK UISACR were compared with the results from the comparator. The match rate between the subject device and predicate device was within the pre-defined acceptance criteria, exact match rate >85%, and within one block match rate >95%.

Conclusions:

The results of the analytical performance studies show that the QSCHECK UISACR was as safe and effective as the predicate device, ACR | LAB Urine Analysis Test System (k182384), demonstrating substantial equivalence.