May 25, 2018

Scanadu Inc.
Daya Ranamukhaarachchi
VP Regulatory & Clinical Affairs
1196 Borregas Ave., Ste 200
Sunnyvale, CA 94089

Re: K180356
Trade/Device Name: inui In-Home Urine Analysis Test System
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIR, LJX, JMT, JIN
Dated: April 19, 2018
Received: April 19, 2018

Dear Daya Ranamukhaarachchi:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180356

Device Name

inui In-Home Urine Analysis Test System

Indications for Use *(Describe)*

The inui In-Home Urine Analysis Test System consists of the inui In-Home Urine Analysis Device and the inui Urine Analysis Mobile Application. The inui In-Home Urine Analysis Test System is intended for detecting the following parameters in urine: Protein, Glucose, Leukocytes, Nitrites, and Ketones. The test results provide information regarding the status of Urinary Tract Infections (UTI), proteinuria, glucosuria, and ketonuria. These results can be used as an aid for monitoring kidney functions and metabolic disorders (e.g. diabetes mellitus), and can be used in the screening for Urinary Tract Infections (UTI).

The inui In-Home Urine Analysis Device is intended for use as a prescription home use device.

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.

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510(k) Summary
K180356

The following 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Preparation date: May 23, 2018

2. Owner/Submitter Information:

Scanadu, Inc.
1196 Borregas Ave., Suite 200
Sunnyvale, CA 94089

Daya Ranamukhaarachchi, PhD
VP Regulatory & Clinical Affairs
daya.ranamukhaarachchi@scanadu.com

Phone: (650) 919-8861

3. Device Information
   a. Proprietary Name: inui In-Home Urine Analysis Device
   b. Common name: Urinalysis Test
   c. Classification Number: See Regulatory Classification below
   d. Classification Panel: Clinical Chemistry

4. Predicate Device Information

Device Name	Multistix® 10 SG Test Strips
Manufacturer	Siemens Inc.
510(k) number	# K992257

5. Regulatory Classification

   The regulatory information for the Inui In-Home Urine Analysis Device is listed below:

   Medical Device Panel: Clinical Chemistry

   Regulatory Classification: The regulatory classification information for the specific analytes tested in the Inui In-Home Urine Analysis Device is listed in Table 1.

Table 1. Regulatory Classification for Scanadu Urinalysis Device

Test Description	Product Code	Device class*	Regulation
Leukocyte peroxidase test	LJX	Class I	21 CFR §864.7675
Urinary protein or albumin (non-quantitative) test system	JIR	Class I	21 CFR §862.1645
Nitrite (non-quantitative) test system	JMT	Class I	21 CFR §862.1510
Ketones (non-quantitative) test system	JIN	Class I	21 CFR §862.1435
Urinary Glucose (non-quantitative) test system	JIL	Class II	21 CFR §862.1340

6. Device Description

The inui In-Home Urine Analysis Test System consists of inui In-Home Urine Analysis Device and the inui Urine Analysis Mobile Application. It is an in vitro diagnostic device comprised of a disposable test paddle, a urine collection cup, a gray background sheet, and a mobile application ("inui App"). The plastic "paddle" contains multiple chemistry test pads (CTPs) and 1 quick response (QR) barcode. CTPs contain pre-dried chemicals that react to specific substances in a urine sample. A color reaction occurs on the CTP based on the amount of substance in the urine sample. The color reaction is captured as an image using the mobile device camera and should only be read using the inui App. The results are reported as specified by the measurement range for each test. The QR Code is used for quality control purposes to track lot number, expiration date, and paddle use.

The inui In-Home Urine Analysis System reports semi-quantitative or qualitative results for each test parameters. Table 2 provides reported levels for each parameter tested in inui Device.

Table 1. Reported Levels for parameters tested in inui Device

Urine Analytes	Results
Protein	Negative
	Trace [15 mg/dL]
	Moderate [30(+) mg/dL]
	Large [100(++) –2000(++++) mg/dL]
Glucose	Negative
	Low [100 mg/dL]
	Moderate to Large [250(+) –2000(++++) mg/dL]
Leukocytes	Negative
	Positive

Urine Analytes	Results
Nitrites	Negative
	Positive
Ketones	Negative [0-5 mg/dL]
	Small [15 mg/dL]
	Moderate to Large [40-160 mg/dL]

7. Indications and Intended Use

   The inui In-Home Urine Analysis Test System consists of inui In-Home Urine Analysis Device and the inui Urine Analysis Mobile Application. The inui In-Home Urine Analysis Test System is intended for detecting the following parameters in urine: Protein, Glucose, Leukocytes, Nitrites, and Ketones. The test results provide information regarding the status of Urinary Tract Infections (UTI), proteinuria, glucosuria, and ketonuria. These results can be used as an aid for monitoring kidney functions, metabolic disorders (e.g. diabetes mellitus), and can be used in the screening for urinary tract infections (UTI).

   The inui In-Home Urine Analysis Device is intended for use as a Prescription Home use device.

8. Substantial Equivalence

   Substantial equivalence has been established using the predicate device Multistix 10SG Reagent Test Strips (K992257). As with the predicate device, the proposed device is intended for detecting specific urine analytes using the colorimetry methods that are used in other urinalysis devices. The specific differences to the indications include (1) Prescription Home-use vs. Prescription use, (2) use of the device with a mobile application supported by a mobile device, and (3) only a subset of substances (Protein, Glucose, Leukocytes, Nitrites, and Ketones) tested in the predicate devices are tested in inui Device.

   Summary of the similarities and differences between the predicate device and Inui In-Home Urine Analysis Device is provided in Table below:

Table 2. Substantial Equivalence between Inui In-Home Urine Analysis Device and Multistix 10SG Reagent Strips Predicate device

Area of Comparison	inui In-Home Urine Analysis Device (K180356)	Multistix® 10 SG Test Strips (K992257)
Indications for Use	The inui In-Home Urine Analysis Device is intended for detecting the following parameters in urine: Protein, Glucose, Leukocytes, Nitrites, and Ketones. The test results provide information regarding the status of Urinary Tract Infections (UTI), proteinuria, glucosuria, and ketonuria. These results can be used as an aid for monitoring kidney functions, metabolic disorders (e.g. diabetes mellitus), and can be used in the screening for urinary tract infections (UTI). The inui In-Home Urine Analysis Device is intended for use as a Prescription Home use device. The inui In-Home Urine Analysis Device is intended for use with the inui Urine Analysis Mobile Application supported by mobile phone devices.	Intended for use in at-risk patient groups to assist diagnosis in the following areas: kidney function, carbohydrate metabolism (e.g., diabetes mellitus), urinary tract infections and liver function. The reagent strips also measure physical characteristics, including acid-base balance and urine concentration. The test results can be used along with other diagnostic information to rule out certain disease states.
Device users	Prescription home use by lay users	In near-patient (point-of-care) and centralized laboratory locations.
Chemical Substances Detected	Protein, Glucose, Leukocyte, Nitrite, and Ketone	Leukocytes, Protein, Nitrites, Blood, Ketones and Glucose, Creatinine, Specific Gravity, pH, Bilirubin, Urobilinogen
Target Population	Adults	Same
Intended specimen	Urine	Same
Materials Provided	Chemical Test Pads affix to a plastic paddle; Urine collection cup; Mobile phone App; Gray background sheet	Chemical Test Pads affixed to a firm plastic strip

Test Time	All analytes are read at once in 1 minute	Analytes are read at different times up to 2 minutes
Detection	Image capture by mobile phone digital camera	Visual read by trained professionals
Results determination	Electronic color analysis via Mobile phone App	Visual comparison to color chart or machine read
Urine analyte detection methodology	Based on color change resulting from the reaction of urine analytes on test pads	Same
Storage	56 – 86°F (15 – 30°C)	Same

9. Assessment of Analytical Performance

This Section details the Precision and Reproducibility, Limit of Detection, and Specificity (Interference testing) studies conducted in accordance with the applicable Clinical Laboratory Standards Institute (CLSI) standards.

a. Precision and Reproducibility

The precision and reproducibility testing was conducted in accordance with CLSI guidelines as applicable for qualitative and semi-quantitative assays. The precision and reproducibility was evaluated with two studies: repeatability (within run) and reproducibility (between run).

The proportion of agreement for each level and analyte tested met the established acceptance criteria and was found to be above 95% agreement to the expected values for both precision and reproducibility.

b. Limit of Detection and Linearity

The purpose of this study was to establish the Limit of Detection (LOD) and Linearity of inui In-Home Urine Analysis device. The test measurements are considered either semi-quantitative or qualitative depending on the analyte. The LOD for each level and analyte were determined based on the established protocol and the results generated separately for each analyte. Summary of the sensitivities are provided in Table 3.

c. Specificity and Interference Testing

The study design was developed in accordance with CLSI guidelines as applicable for qualitative and semi-quantitative assays. Thirty-nine potentially interfering exogenous and endogenous substances were evaluated. Substances that cause abnormal urine color may affect the readability of the chemistry test pads by the App. The inui device has built-in additional precautions: it produces an error message with no result (invalid) for any substance that introduces colors outside the range for that analyte. Extreme concentrations of substance such as Acetoacetic

Acid at all tested concentrations consistently produced an error message.

The results with the interfering substances and the minimum concentration level tested that produced false positives and false negatives are provided in Table 4 for each analyte and level.

Table 3. Summary of sensitivities for five urine analytes

Analyte	**Tested Levels**			
Protein	Below 10 mg/dL (Negative)	10 mg/dL to below 23 mg/dL (Trace)	23 mg/dL to below 60 mg/dL (Moderate)	60 mg/dL and above (Large)
Glucose	Below 50 mg/dL (Negative)	50 mg/dL and below 175 mg/dL* (Low)	175 mg/dL and above (Moderate-Large)	NA
Leukocyte	Below 0.0023 U/ml (Negative-Trace)	0.0023 U/ml and above (Small-Large)	NA	NA
Nitrite	Below 0.025 mg/dL (Negative)	0.025 mg/dL and above (Positive)	NA	NA
Ketone	Below 10 mg/dL (Negative-Trace)	10 mg/dL and below 28 mg/dL (Small)	28 mg/dL and above (Moderate-large)	NA

Table 4. Summary Table depicting Interfering substances and their levels for each analyte

Definitions:

Positive interference: A test result, which incorrectly indicates that a particular condition or attribute is present.

Negative interference: A test result, which incorrectly indicates that a particular condition or attribute is absent.

Analyte	**Negative Control (Positive Bias/Increase in Response)**	**Positive Control (Negative Bias/Decrease in Response)**
Protein	Albumin HSA (>3000 mg/dL) (Expected Interferent)	Acetoacetic Acid (invalid results at all conc)
	Bilirubin (>10 mg/dL)	Hypochlorite (>375 mg/dL)
	Hemoglobin (>100 mg/dL)	
	Chlorhexidine (>40 mg/dL)	Specific Gravity (>1.025)
	Riboflavin (>5 mg/dL)	

Leukocyte	Human Leukocyte Esterase (>0.025 U/mL) (Expected Interferent)	Acetoacetic Acid (invalid results at all conc)
		Albumin HSA (>3000 mg/dL)
		Bilirubin (>10 mg/dL)
		Sodium Chloride (>324 mg/dL)
		Hypochlorite (>375 mg/dL)
	Hemoglobin (>150 mg/dL)	Chlorhexidine (>60 mg/dL)
		Microbial Peroxidase (>0.65%)
		Riboflavin (>5 mg/dL)
		Sodium Acetate (>600 mg/dL)
		Sodium Bicarbonate (>630 mg/dL)
		Specific Gravity (>1.020)
		Urobilinogen (>4 mg/dL)
Nitrite	Sodium Nitrite (>5 mg/dL) (Expected Interferrent)	Sodium Bicarbonate (>945mg/dl)
	Human Hemoglobin (>100 mg/dL)	
	Hypochlorite (>375 mg/dL)	
	Human Leukocyte (>0.0375 U/mL)	Sodium Acetate (>900 mg/dL)
	Urobilinogen (>4 mg/dl)	
Ketone	Lithium Acetoacetate (>40 mg/dL) (Expected Interferrent)	Hypochlorite (>375 mg/dL)
		Sodium Nitrite (>7.5 mg/dL)
		Acetoacetic Acid (invalid results at all conc)
Glucose	D-(+)-Glucose (>500 mg/dL) (Expected Interferrent)	Acetoacetic Acid (invalid results at all conc)
	Hypochlorite (>375 mg/dL)	Lithium Acetoacetate (>80 mg/dL)
	Bilirubin (Invalid results at all conc)	Sodium Chloride (>486 mg/dL)

10. Assessment of Clinical Performance

    A clinical accuracy (i.e. method comparison) was established based on the agreement between the results obtained from the inui Device in the hands of the lay-users and the results from the predicate device, Siemens Multistix® 10SG device (K992257), by professional users. Two-method comparison studies were conducted using 190 and 91 lay users following an Investigational Review Board approved clinical protocol. Testing performed via clinical evaluation demonstrated that typical lay users between the ages of 18 and 71 can obtain clinical test results that are comparable to those of a professional users using a visual read method, as shown in the table 5.

Additionally, a usability study with 45 lay users was conducted to evaluate their ability to perform urine testing with instructions given in the inui App and the instructions for use provided with the inui Device. Each lay user tested three paddles provided in the device kit. The usability testing produced an overall performance of 88.9%, 86.7%, and 91.1% for the first, second and third paddle, respectively, confirming that the lay users can follow the entire procedural steps (from sign-in and, test set-up to understanding the results) to obtain a successful test result.

In addition, a lay-user reproducibility study with 10 lay users was conducted to evaluate the ability of the lay-user to perform urine testing and obtain the same result after repeated testing. User reproducibility testing demonstrated that the reproducibility of the inui Device in the hands of the lay user was 100%.

Table 5. Agreement of lay user test results with the predicate device and professional user testing

Analyte	**Level**	**Lay User vs Predicate Device**	
		% Agreement (Exact Match)	**% Agreement (within one Color Block)**
Protein	Negative	83	100
	Trace 15 mg/dL	75	100
	Moderate 30(+) mg/dL	90	100
	Large 100(++)–2000(++++) mg/dL	100	100
Glucose	Negative	100	100
	Low 100 mg/dL	74	100
	Moderate to Large 250(+)–2000(++++)	100	100
Leukocyte	Negative	100	N/A
	Positive	97	N/A
Nitrite	Negative	96	N/A
	Positive	100	N/A
Ketone	Negative/ Trace 0-5 mg/dL	99	100
	Small 15mg/dL	67	100
	Moderate to Large 40-160 mg/dL	100	100

11. Conclusion

Analytical performance testing and clinical studies, including lay user testing, usability testing, and reproducibility testing demonstrated that the Inui In-Home Urine Analysis Device is safe and effective, and lay users can use the device. Based on these data, the Inui In-Home Urine Analysis Device is substantially equivalent to the Siemen's Multistix device (K992257).