510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K210069

B Applicant

Healthy.io Ltd.

C Proprietary and Established Names

Minuteful- Kidney Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JFY	Class II	21 CFR 862.1225 - Creatinine test system	CH - Clinical Chemistry
JIR	Class I	21 CFR 862.1645 - Urinary Protein Or Albumin (Nonquantitative) Test System	CH - Clinical Chemistry
KQO	Class I	21 CFR 862.2900 - Automated urinalysis system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Albumin and Creatinine in urine

C Type of Test:

Semi-quantitative urinalysis

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Minuteful - kidney test is an in-vitro diagnostic, home-use urine analysis test system for the semi-quantitative measurement of albumin and creatinine in urine, as well as the presentation of their ratio, the albumin-creatinine ratio (ACR). The system consists of a smartphone application, proprietary Color-Board and an ACR Reagent Strip. The system is available for prescription-use only and is intended for people at risk of kidney disease. Results are intended to be used in conjunction with clinical evaluation as an aid in the assessment of kidney health.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For In Vitro Diagnostics Use Only

D Special Instrument Requirements:

The following representative smartphone models and operating system (OS) versions were used in different studies as described in Section VII Performance Characteristics.

Manufacturer	Model	OS† version
Apple	iPhone 11	iOS 13
Apple	iPhone 13	iOS 15
Apple	iPhone 7	iOS 12
Apple	iPhone 12 Pro MAX	iOS 14
Apple	iPhone SE	iOS 15
Google	Pixel 3a	Android 11
LG	G5	Android 6
Motorola	G100	Android 11
Motorola	G10	Android 11
Nokia	5.3	Android 11
OnePlus	3	Android 8
Samsung	S21 Ultra	Android 11
Samsung	Z Flip 3	Android 11
Samsung	note 8	Android 8
Samsung	a02s	Android 11
Samsung	S9	Android 10

†Operating System

Phones and OS versions that are not compatible with the Minuteful – kidney test will be blocked from downloading the application.

IV Device/System Characteristics:

A Device Description:

The device is provided as a kit that comprises a single YD Diagnostics URiSCAN 2 ACR Urine strips (YD Diagnostics Corporation, k141874), 1 single-use Color-Boards, and a User Manual. The Minuteful – kidney test also consists of a smartphone application for use on the home users' smartphone, and an image recognition algorithm running on a back-end, cloud-based server.

ACR results are reported to both the home user and the prescribing physician.

The individual albumin and creatinine results are reported only to the prescribing physician.

B Principle of Operation:

The albumin test is based on sulfonephthalein dye binding to albumin at a constant pH. The development of pale green to aqua blue indicates the presence of albumin. The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'- tetramethylbenzidine. The resulting color ranges from orange through green to blue.

The Minuteful – kidney test scans and analyzes the test strip using a mobile device running the smartphone application.

C Instrument Description Information:

1. Instrument Name:
   Minuteful - kidney test

2. Specimen Identification:
   The Minuteful kidney-test application will instruct the user to enter their patient identification information in the application.

3. Specimen Sampling and Handling:
   The test is performed using midstream urine sample collected in a cup.

4. Calibration:
   Calibration is not needed.

5. Quality Control:
   The device has internal controls and no external quality controls are provided.

V Substantial Equivalence Information:

A Predicate Device Name(s):

URiSCAN Optima urine chemistry test system

B Predicate 510(k) Number(s):
K141874

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210069	K141874
Device Trade Name	Minuteful - kidney test	URiSCAN Optima urine chemistry test system
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intend for the semi-quantitative measurement of albumin and creatinine in urine, as well as the presentation of their ratio, the albumin-creatinine ratio (ACR).	Same
Test Specimen	Urine	Same
General Device Characteristic Differences		
Intended User	Lay user	Professional user
Environment Used	Home environment	Laboratories/Clinical

VI Standards/Guidance Documents Referenced:

- Clinical and Laboratory Standards Institute (CLSI) EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures, Approved Guidelines, Third Edition
- CLSI EP07: Interference Testing in Clinical Chemistry, Third Edition
- CLSI EP37: Supplemental Tables for Interference Testing in Clinical Chemistry – First Edition
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, Approved Guideline, Second Edition
- ANSI AAMI IEC, 62366-1: 2015+AMD1:2020: Medical devices Part 1: Application of usability engineering to medical devices
- ANSI AAMI IEC, 62304:2006/A1:2016, Medical device software-Software life cycle Processes
- ISO 14971:2019, Medical devices- Application of risk management to medical devices

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Testing was conducted with 3 urine samples. Each urine sample was produced by spiking negative urine with albumin and creatinine to the following expected reporting levels: 10 mg/L, 30-80 mg/L, and 150 mg/L albumin; 10 mg/dL, 50 mg/dL, and 200-300 mg/dL creatinine; Normal, Abnormal, and High-Abnormal ACR. Testing was conducted by 3 operators over 3 days at 3 sites using 3 device lots per site. Each device lot was used to test each of the 3 urine samples in 2 runs per day with 3 replicates per run. All testing was conducted with 1 iPhone 11 and 1 Pixel 3a per site. Repeatability was calculated using the results from all of the replicates from the first run of the first day. Reproducibility was calculated using all replicates across the entire study.

Repeatability (iPhone 11 and Pixel 3a results combined)

ACR							
		Normal	Abnormal	High-Abnormal	Overall	Overall 95% CI Low	Overall 95% CI High
Exact Match	Count	54	54	54	162	97.8	100
	%	100%	100%	100%	100%		
±1 Color Block	Count	54	54	54	162	97.8	100
	%	100%	100%	100%	100%		

Albumin							
		10 mg/L	30-80 mg/L	150 mg/L	Overall	Overall 95% CI Low	Overall 95% CI High
Exact Match	Count	54	54	54	162	97.8	100
	%	100%	100%	100%	100%		
±1 Color Block	Count	54	54	54	162	97.8	100
	%	100%	100%	100%	100%		

Creatinine							
		10 mg/dL	50 mg/dL	200-300 mg/dL	Overall	Overall 95% CI Low	Overall 95% CI High
Exact Match	Count	54	54	54	162	97.8	100
	%	100%	100%	100%	100%		
±1 Color Block	Count	54	54	54	162	97.8	100
	%	100%	100%	100%	100%		

Reproducibility (iPhone 11 and Pixel 3a results combined)

ACR							
		Normal	Abnormal	High-Abnormal	Overall	Overall 95% CI Low	Overall 95% CI High
Exact Match	Count	324	324	324	972	99.6	100
	%	100%	100%	100%	100%		
±1 Color Block	Count	324	324	324	972	99.6	100
	%	100%	100%	100%	100%		

Albumin							
		10 mg/L	30-80 mg/L	150 mg/L	Overall	Overall 95% CI Low	Overall 95% CI High
Exact Match	Count	324	324	324	972	99.6	100
	%	100%	100%	100%	100%		
±1 Color Block	Count	324	324	324	972	99.6	100
	%	100%	100%	100%	100%		

Creatinine							
		10 mg/dL	50 mg/dL	200-300 mg/dL	Overall	Overall 95% CI Low	Overall 95% CI High
Exact Match	Count	324	324	324	972	99.6	100
	%	100%	100%	100%	100%		
±1 Color Block	Count	324	324	324	972	99.6	100
	%	100%	100%	100%	100%		

In addition to the studies described above, the sponsor also conducted a 20-day precision study in which spiked urine samples with 3 levels of albumin (expected values 10 mg/L, 30-

80 mg/L, and 150 mg/L), creatinine (expected values 10 mg/dL, 50 mg/dL, 200-300 mg/dL), and ACR (Normal, Abnormal, and High-Abnormal) were tested by 3 operators in singlicate at 3 sites with 2 runs per day using 3 device lots with 1 iPhone and 1 Pixel 3a per site. The results were similar to the results in the studies described above.

2. Linearity:

Testing was conducted with urine samples spiked to 4 levels of creatinine (expected outputs of 10, 50, 100, and 200-300 mg/dL), 3 levels of albumin (expected outputs of 10, 30-80, and 150 mg/L), and 3 levels of ACR (expected outputs of Normal, Abnormal, and High-Abnormal). The study was performed by three (3) different operators, using three (3) different strip lots with ten (10) replicates per lot. The study was conducted using iPhone 11 and Pixel 3a devices.

Albumin-Creatinine Ratio		
ACR Output	% Exact Match	% ±1 Color Block
Normal	100	100
Abnormal	100	100
High-Abnormal	100	100

Albumin		
ALB Output (mg/L)	% Exact Match	% ±1 Color Block
10	100	100
30-80	100	100
150	100	100

Creatinine		
CRE Output (mg/dL)	% Exact Match	% ±1 Color Block
10	100	100
50	100	100
100	100	100
200-300	100	100

3. Analytical Specificity/Interference:

Interference testing was conducted per recommendations in *CLSI EP07 Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition*. Negative urine was spiked with 3 levels of albumin (expected outputs of 10, 30-80, and 150 mg/L) and creatinine (expected outputs of 10, 50, and 200-300 mg/dL) to produce test samples with 3 levels of ACR (expected outputs of Normal, Abnormal, and High-Abnormal). Test samples were spiked with interfering substance or the same volume of diluent (control samples). The concentrations of interfering substances tested were higher than the concentrations of these substances expected to be in urine samples from the intended use population. Testing was conducted with 1 device lot on the Apple iPhone 11 and Google Pixel 3a and 10 replicates

were tested at each test level with each potentially interfering substance. The results of the test samples with interfering substance were compared to the results of the control samples and no interference was defined as 100% agreement (10/10) between the sample with potential interferent and control samples. If interference was observed, additional testing was conducted to determine the lowest concentration of the interfering substance that shows interference and the highest that does not show interference.

The results of the interference study are summarized below.

Potential Interfering Substance	Measurand	Highest Concentration of Potentially Interfering Substance at Which no Interference Observed
Acetominophen	ACR	300 mg/dL
	Albumin	300 mg/dL
	Creatinine	300 mg/dL
Albumin	ACR	N/A
	Albumin	N/A
	Creatinine	880 mg/dL
Ascorbic Acid	ACR	440 mg/dL
	Albumin	440 mg/dL
	Creatinine	220 mg/dL
Bilirubin	ACR	6 mg/dL
	Albumin	6 mg/dL
	Creatinine	6 mg/dL
Caffeine	ACR	37 mg/dL
	Albumin	37 mg/dL
	Creatinine	37 mg/dL
Blood	ACR	0.05%
	Albumin	0.05%
	Creatinine	0.05%
Calcium Chloride	ACR	210 mg/dL
	Albumin	210 mg/dL
	Creatinine	210 mg/dL
Capotopril	ACR	12 mg/dL
	Albumin	12 mg/dL
	Creatinine	12 mg/dL
Citric Acid	ACR	100 mg/dL
	Albumin	100 mg/dL
	Creatinine	100 mg/dL
Creatinine	ACR	N/A
	Albumin	750 mg/dL

Potential Interfering Substance	Measurand	Highest Concentration of Potentially Interfering Substance at Which no Interference Observed
	Creatinine	N/A
Cyanocobalamin (Vitamin B12)	ACR	0.16 mg/dL
	Albumin	0.16 mg/dL
	Creatinine	0.16 mg/dL
Dapagliflozin	ACR	0.03 mg/dL
	Albumin	0.03 mg/dL
	Creatinine	0.03 mg/dL
Fructose	ACR	100 mg/dL
	Albumin	100 mg/dL
	Creatinine	100 mg/dL
Glucose	ACR	5000 mg/dL
	Albumin	5000 mg/dL
	Creatinine	5000 mg/dL
Glycine	ACR	450 mg/dL
	Albumin	450 mg/dL
	Creatinine	450 mg/dL
Hemoglobin	ACR	6.8 mg/dL
	Albumin	6.8 mg/dL
	Creatinine	6.8 mg/dL
Hydrochlorothiazide	ACR	5 mg/dL
	Albumin	5 mg/dL
	Creatinine	5 mg/dL
Hydroxychloroquine sulfate	ACR	4 mg/dL
	Albumin	4 mg/dL
	Creatinine	8 mg/dL
Iron Sulfate	ACR	24 mg/dL
	Albumin	24 mg/dL
	Creatinine	24 mg/dL
Acetoacetic Acid	ACR	300 mg/dL
	Albumin	300 mg/dL
	Creatinine	300 mg/dL
Leukocytes	ACR	2500 leukocytes/µL
	Albumin	2500 leukocytes/µL
	Creatinine	2500 leukocytes/µL
Losartan	ACR	5 mg/dL
	Albumin	5 mg/dL

Potential Interfering Substance	Measurand	Highest Concentration of Potentially Interfering Substance at Which no Interference Observed
	Creatinine	5 mg/dL
Metformin Hydrochloride	ACR	285 mg/dL
	Albumin	285 mg/dL
	Creatinine	285 mg/dL
Phenolphthalein	ACR	1060 mg/dL
	Albumin	1060 mg/dL
	Creatinine	1060 mg/dL
Potassium Chloride	ACR	1990 mg/dL
	Albumin	1990 mg/dL
	Creatinine	1990 mg/dL
Riboflavin	ACR	20 mg/dL
	Albumin	20 mg/dL
	Creatinine	20 mg/dL
Sodium Acetate	ACR	260 mg/dL
	Albumin	260 mg/dL
	Creatinine	260 mg/dL
Sodium Bicarbonate	ACR	975 mg/dL
	Albumin	975 mg/dL
	Creatinine	975 mg/dL
Sodium Chloride	ACR	5100 mg/dL
	Albumin	5100 mg/dL
	Creatinine	5100 mg/dL
Sodium Nitrite	ACR	9 mg/dL
	Albumin	9 mg/dL
	Creatinine	9 mg/dL
Sodium-2-mercaptoethanesulfonate (Mesna)	ACR	750 mg/dL
	Albumin	750 mg/dL
	Creatinine	190 mg/dL
Theophylline	ACR	100 mg/dL
	Albumin	100 mg/dL
	Creatinine	100 mg/dL

The sponsor is including the table below with the statement “In addition, the ACR result may be falsely elevated in patients taking sodium bicarbonate and/or hydroxychloroquine in high concentrations” in the Physician Compendium to describe the impact of the observed interferences on the device.

Analyte/ measurand	Interfering substance	Lowest tested concentration causing an interference	Interference effect
Albumin	Sodium bicarbonate	1,300 mg/dL	Falsely increased
	Hydroxychloroquine sulfate	6 mg/dL	
Creatinine	Mesna	380 mg/dL	Falsely decreased
	Ascorbic acid	330 mg/dL	
	Sodium bicarbonate	1,300 mg/dL	
ACR	Sodium bicarbonate	1,300 mg/dL	Falsely increased
	Hydroxychloroquine sulfate	6 mg/dL	

To inform the lay user about potential interference, the User Manual contains the statements, "Do not use the device in the case of a discolored urine specimen. If the color of your urine is different than yellow or clear, do not use this test and consult with your healthcare professional" and "The substances that have been shown to interfere include: Ascorbic acid (Vitamin C), mesna (MESNEX), sodium bicarbonate and hydroxychloroquine sulfate (PLAQUENIL®). If you are taking these medications or supplements, please inform your physician."

Specific Gravity (SG)
The test urine samples were adjusted to specific gravities of 1.000, 1.005, 1.010, 1.015, 1.025, 1.035, and 1.045. No interference on albumin, creatinine or ACR was observed at the urine specific gravities tested.

pH
The test urine samples were adjusted to pH levels of 4, 5, 6, 7, 8, and 9. No interference on albumin, creatinine or ACR was observed at the urine pH levels tested.

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The sponsor's device is traceable to a legally marketed urine ACR device. The sponsor's traceability scheme was reviewed and found acceptable.

5. Detection Limit/Cutoffs:

The sponsor collected a total of 57 urine samples from subjects with Diabetes Mellitus Type II, Hypertension, Dyslipidemia, Cardiovascular disease, a known kidney disease (e.g., Nephrolithiasis, Congenital abnormalities of the kidney and urinary tract, Diabetic nephropathy), Malignancy (e.g., Renal cell carcinoma), Autoimmune disease and Tobacco use disorder. The median age of this population was 62. The samples were pooled and diluted with negative urine to produce different levels of albumin and creatinine. Albumin and creatinine were measured in test samples using a commercially available device that quantitatively measures albumin and creatinine in urine.

The sponsor conducted testing with 1 lot of their device. Several samples with albumin and creatinine levels around the cutoffs were tested and the sponsor used a Probit model described in the CLSI EP17-A2 guideline to estimate the C5, C50 and C95 for each of the cutoffs. Testing was conducted with 16 representative smartphones.

The sponsor's study supports that the cutoffs between the albumin and creatinine categories are the same when the test is used with different smartphones and operating systems.

6. Assay Cut-Off:
   Not Applicable.

7. Accuracy (Instrument):
   See Section B.1. Method Comparison

8. Carry-Over:
   See Section F. Other Supportive Instrument Performance Characteristics Data

B Comparison Studies:

1. Method Comparison with Predicate Device:

A total of 466 subjects (263 males and 203 females) 18 to 81 years of age were enrolled to assess the performance of the sponsor's device. Study subjects were lay users and included those with hypertension, Type 2 Diabetes, dyslipidemia, cardiovascular disease and kidney disease. Subjects tested their own urine samples with the sponsor's device using an iPhone 11 or Google Pixel 3a following the user manual and in-application prompts. The subjects' urine samples were then tested by a trained operator using the predicate device. The trained operator was blinded to the results from the sponsor's device. The results from the sponsor's device were compared with the results from the predicate device. The results are summarized in the tables below.

ACR	Comparator device				
Minuteful Kidney test	Reported block	Normal	Abnormal	High Abnormal	Total
	Normal	254 92.0%	5 3.0%	-	259
	Abnormal	22 8.0%	158 94.0%	2 9.1%	182
	High Abnormal	-	5 3.0%	20 90.9%	25
	Total	276	168	22	466
	Exact match	92%	94%	90.9%	92.7%

Albumin	Comparator Device					
Minuteful - Kidney Test	Reported blocks	10	30	80	150	Total
	10	220 92.8%	2 2.4%	-	-	222
	30,80	17 7.2%	82 97.6%	67 84.8%	6 9.1%	172
	150	-	-	12 15.2%	60 90.9%	72
	Total	237	84	79	66	466
	Exact Match	92.8%	91.4%		90.9%	92.1%

Creatinine	Comparator Device						
Minuteful - Kidney Test	Reported blocks	10	50	100	200	300	Total
	10	43 95.6%	9 5.8%	-	-	-	52
	50	2 4.4%	139 89.7%	16 9.2%	-	-	157
	100	-	7 4.5%	145 83.3%	7 22.6%	1 1.6%	160
	200,300	-	-	13 7.5%	24 77.4%	60 98.4%	97
	Total	45	155	174	31	61	466
	Exact Match	95.6%	89.7%	83.3%	91.3%		88.2%

Usability Results

All 466 study participants (100%) completed the Minuteful - kidney test using only the user manual provided in the kit and the device in-app guides to test their own urine. The subjects rated the overall ease of use of the Minuteful – kidney test on a scale of 1 (very hard) to 5 (very easy) and the average ease-of-use rating was 4.93, indicating that the subjects found the test easy to use.

2. Matrix Comparison:
Not applicable. This test is only for urine samples.

C Clinical Studies:

1. Clinical Sensitivity:
   Not Applicable

2. Clinical Specificity:
   Not Applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   See Section B.1. Method Comparison with Predicate

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

Minuteful - kidney test ACR Results

	Normal	Abnormal	High Abnormal
Albumin-Creatinine Ratio	< 30 [mg/g] / 3.4 [mg/mmol]	30-300 [mg/g] / 3.4-33.9 [mg/mmol]	> 300 [mg/g] / 33.9 [mg/mmol]

Albuminuria categories are based on ACR (mg albumin per gram of creatinine in a spot urine sample). Categories are based on recommendations in *Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney inter., Suppl. 2013; 3: 1– 150.*

F Other Supportive Instrument Performance Characteristics Data:

The sponsor conducted flex studies with urine samples spiked with albumin and creatinine to three levels of albumin, creatinine, and ACR. The expected results for the three levels of urine samples tested were 10 mg/L, 30-80 mg/L, and 150 mg/L for albumin; 10 mg/dL, 50 mg/dL, and 200-300 mg/dL for creatinine; Normal, Abnormal, and High-abnormal for ACR.

1. Timing

   a) Dipping Time

   Strips were dipped in the test urine samples for two different time durations, 1 second (the control dipping time) and 10 seconds. Wetting ("blotting") and assay times (time between blotting and scanning) were <1 second and 75 seconds, respectively. Testing was conducted with two representative smartphones of different models and operating systems (iPhone 11 and Pixel 3a). The results support that dipping for up to 10 seconds does not impact test performance. The Minuteful kidney – test application guides the user through each step of the testing procedure and instructs the user to dip the strip for 1 second.

b) Blotting Time

Strips were dipped in the test urine samples for 1 second and either blotted for <1 second (control) or blotted for 75 seconds (test). Testing was conducted with two representative smartphones of different models and operating systems (iPhone 11 and Pixel 3a). The results support that blotting times for up to 75 seconds do not impact test performance. The Minuteful kidney – test application guides the user through each step of the testing procedure and instructs the user to blot the strip for 1 second.

c) Assay Time

Strips were dipped in the test urine samples for 1 second and blotted for <1 second. The assay time (time between blotting and scanning the strip with the smart phone) were 75 seconds (the control assay time) and 180 seconds (test assay time). Testing was conducted with two representative smartphones of different models and operating systems (iPhone 11 and Pixel 3a). The results support that assay times for up to 180 seconds do not significantly impact test performance. The Minuteful kidney – test application guides the user through each step of the testing procedure and instructs the user to take a picture of the test strip and Color-Board within 3 minutes (180 seconds) of blotting the test strip. If the assay time exceeds 180 seconds, the application prevents the user from completing the test.

2. Carry-Over

Strips were held in both the "up" (with albumin on top) and "down" (with creatinine on top) positions for 0 (control), 10, 25 and 40 seconds after being dipped in solutions and before blotting. In the "up" experiment, a solution comprised of 150 mg/L albumin and 10 mg/dL creatinine, was used. In the "down" experiment, a solution comprised of 200-300 mg/dL creatinine and 10 mg/L albumin, was used. Dipping and assay times were 1 and 75 seconds, respectively. The wetting (“blotting) time corresponded to the time the strip will be held in the “up” or “down” position (nested factors). Testing was conducted with two representative smartphones of different models and operating systems (iPhone 11 and Pixel 3a). The results support that the performance is not impacted by potential carry-over from one reagent pad to the other. The Minuteful kidney – test application guides the user through each step of the testing procedure and instructs the user to blot the test strip immediately after dipping and place it on the Color-Board.

3. Illumination

a) Testing was conducted under different lighting conditions of different color “temperatures” and intensities from different light sources representative of those that may be used in the home setting. Testing was conducted with 16 representative smart phones of different models using different operating systems. The results of the study support that the performance is not impacted by lighting conditions that are likely to be found in the home use environment.

b) Testing was conducted under different lighting conditions with different saturation of red, green, and blue light. Testing was conducted with 16 representative phones of different models and operating systems. Phones were tested under “boundary conditions” that were

the maximum saturation of red, green, or blue light under which the device allowed the phone to take a picture of the urine test strip and color-board (under red, green, or blue light saturation that exceeded the boundary conditions, the application blocks the user from taking a picture). The results of this testing support that the device performance is not impacted by different light color saturation.

c) Testing was conducted under different light intensities (darkness and brightness measured in lux). Testing was conducted with 16 representative phones of different models and operating systems. Phones were tested under "boundary conditions" of light intensity that were the minimum light intensity and the maximum light intensity at which the device allows the phone to take a picture of the color board and urine test strip (under lighting conditions that exceeded the "boundary conditions" of light intensity i.e., darkness or brightness, the application blocks the user from taking a picture). The results of this testing support that the device is not impacted by different light intensities.

4. Distance and Angle

Testing was conducted with 16 representative smart phones of different models and operating systems. Each phone was tested under "boundary conditions" that were 2 different distance conditions and 2 different angle conditions. The distance conditions were the longest distance from the color board and the shortest distance from the color board at which the device allowed the phone to take a picture of the strip and color board (at longer or shorter distances, the device blocks the user from taking a picture). The angle conditions were the most acute and most obtuse angles at which the device allowed the phone to take a picture of the urine test strip and color board (at more acute or obtuse angles, the device blocks the user from taking a picture). The performance of the device was not impacted under these "boundary conditions".

5. Shadow

Testing was conducted with 16 representative smart phones of different models and operating systems under different shadow configurations of different intensity and covering different portions of the color-board and urine test strip. Six different shadow configurations and 2 different shadow intensities were tested. For 3 of the shadow configurations, the device blocked the user from taking a picture of the color-board and urine test strip. For the other 3 shadow configurations, the device performance was not impacted by the presence of shadows on the color-board and test strip.

6. Blurring

Testing was conducted with 16 representative smart phones of different models and operating systems under 14 different conditions of blurred images consisting of different levels of focus and motion blur. Under conditions that the devices detected too much image blur, the user was blocked from taking a picture of the color-board and the urine test strip. Under conditions where the device allowed a picture of the color-board and urine test strip to be taken, the device performance was not impacted by image blur.

7. Misplaced Urine Stick

   Testing was conducted with 16 representative smart phones of different models and operating systems with 8 different urine test strip placements. Of the 8 different placements, 4 urine test strip placements were recognized as invalid by the device and the device blocked the user from taking a picture of the color-board and urine test strip. When the device determined the stick placement to be valid, variations in stick placement did not impact the performance of the device.

8. Dirty Color-Board

   Testing was conducted with 16 representative smart phones of different models and operating systems. Testing was conducted with 3 substances (urine, coffee, and ink) and 3 different "dirty" configurations covering different sections of the color-board and urine test strip. The device blocked the user from taking a picture of the color-board and urine test strip under "dirty" configurations that the device determined to be invalid. Under the "dirty" conditions the device determined to be valid, the performance of the device was not impacted.

9. Operating Conditions

   Testing was conducted at four different operating conditions: 95% relative humidity (RH) at 35°C, 95% RH at 10°C, 10% RH at 35°C, and 10% RH at 10°C. Testing was conducted using two representative smart phones of different models. The performance of the device was not impacted under the conditions tested.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.