September 8, 2023

Healthy.io Ltd.
Ron Zohar
Chief Product Officer
8 Yitzhak Sadeh St.
Tel Aviv, Israel
6777508

Re: K222921
Trade/Device Name: Minuteful-kidney test
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY, JIR, KQO
Dated: June 11, 2023
Received: June 12, 2023

Dear Ron Zohar:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222921

Device Name
Minuteful - kidney test

Indications for Use *(Describe)*
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.

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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Healthy.io's Minuteful - kidney test
(K222921)

Submitter:

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Contact Person: Ron Zohar

Date Prepared: September 19, 2022

Name of Device: Minuteful - kidney test

Common or Usual Name: Smartphone enabled albumin-creatinine ratio analyzer

Regulation Section and Classification Name:

Class I: Albumin
Class II: Creatinine

21 CFR § 862.1645 Urinary protein or albumin (non-quantitative) test system
21 CFR § 862.1225 Creatinine test system
21 CFR § 862.2900 Automated urinalysis system

Product Code:

JIR	Urinary protein or albumin (nonquantitative) test
system JFY	Creatinine test system
KQO	Automated urinalysis system

Classification Panel: Clinical Chemistry

Predicate Device:

The Minuteful - kidney test is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) Number
Healthy.io Ltd.	Minuteful - kidney test	K210069

Device Description:

The Minuteful - kidney test is comprised of a kit and a smartphone application. It is intended 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 Minuteful - kidney test is intended for prescription-use only, as a home-use device to aid in the assessment of kidney health. The results can be used together with clinical evaluation to guide patient care.

The device's kit includes a urine receptacle, an ACR Reagent Strip, an absorbing (i.e. "blotting") pad, a proprietary Color-Board and a user manual. The device also consists of an easy-to-use smartphone application, image recognition algorithms, and a physician compendium.

The software component of the Minuteful - kidney test consists of both an application (app) and a backend server. Both components encompass different computer vision and machine learning algorithmic components, performing the image analysis activities. The app instructs the user how to accurately administer the test. The Image Validation Transfer System (IVTS) component of the Minuteful - kidney test enables its usage across a wide range of smartphone types and operating systems, essentially making the test platform agnostic.

Intended Use/Indications 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.

Table I Comparison between the Minuteful - kidney test (K222921) and Minuteful - kidney test (K210069) the predicate device.

Feature	Minuteful - kidney test (K210069)	Minuteful - kidney test (K222921)
Intended 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.	Same
Test Specimen	Urine	Same
Detection Methodology	Reflectance photometry	Same
Detection Device	Photosensitive diode	Same
Strips	URiSCAN 2ACR urine strips (K141874)	Same
Analytes	albumin, creatinine	Same
Power Source	Not Applicable	Same
Data Transfer/ Capabilities	Via smartphone internet connection from the backend server to the lay user and a healthcare professional. Results are available for secure sharing	Same

Feature	Minuteful - kidney test (K210069)	Minuteful - kidney test (K222921)
	with an EMR.	
Available languages on screen	English	English, Spanish
Measuring Cycle/Incubation Time	75 seconds	Same
Throughput	Not Applicable	Same
Smartphones/ Operating Systems	The product supports a wide variety of currently available smartphones and operating systems. Newly introduced smartphone-hardware and new operating systems will be validated by the company on a regular basis.	Same
Dimensions	106mm (W) x 143mm (D) x 30mm (H)	Same
Weight	0.105kg	Same

Summary of Performance Data:

Healthy.io conducted multiple validation studies including the Limit of Detection and the set of IVTS studies to ensure the modified device is substantially equivalent to the predicate device (Minuteful - kidney test K210069). The rest of the analytical and clinical performance studies are still relevant for the modified version of the Minuteful - kidney test, and their summary is available in the predicate device documentation (K210069).

Performance Testing:

The performance characteristics of the Minuteful - kidney test were evaluated according to the following performance tests:

Limit of Detection (LoD):
Testing of the Minuteful - kidney test detection limits was designed and executed in accordance with guidance provided by the Clinical and Laboratory Standards Institute (CLSI) document EP17-A2 - Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guidelines - Second Edition.

Illumination Conditions:
This study consisted of two separate studies; the Multiple Illuminations and Extreme Illuminations studies.

- Multiple Illuminations: 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. 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.
- Extreme Illuminations: Testing was conducted under different lighting conditions with different saturation of the RGB spectrums as well as under different light intensities. Tested smartphones were evaluated at the edges of the device boundary conditions, under which the device allowed the smartphone to take an image of the urine test strip and Color-Board. The results of this testing support that the device performance is not impacted by different light color saturations.

Physical Conditions:
Testing was conducted under different distance conditions and different angle conditions. Tested smartphones were evaluated at the edges of the device boundary conditions, under which the device allowed the smartphone to take an image of the urine test strip and Color-Board. The performance of the device was not impacted within the supported conditions.

Multiple Shadow conditions:
Testing was conducted under different shadow configurations of different intensity and covering different portions of the Color-Board and urine test strip. Tested smartphones were evaluated at the edges of the device boundary conditions, under which the device allowed the smartphone to use the captured image of the urine test strip and Color-Board. The performance of the device was not impacted by the presence of shadows on the color-board and test strip within the supported conditions.

Blurriness:
Testing was conducted under different conditions of blurred images consisting of different levels of focus and motion blur. Tested smartphones were evaluated at the edges of the device boundary conditions, under which the device allowed the smartphone to take an image of the urine test strip and Color-Board. The performance of the device was not impacted by the image blur within the supported conditions.

Misplaced Urine Stick:
Testing was conducted under different urine test strip placements. Tested smartphones were evaluated at the edges of the device boundary conditions, under which the device allowed the smartphone to use the captured image of the urine test strip and Color-Board. The performance of the device was not impacted by the test strip placement within the supported conditions.

Dirty Color-Board:
Testing was conducted under different dirty substances covering different parts of the Color-Board. consisting of different levels of focus and motion blur. Tested smartphones were evaluated at the edges of the device boundary conditions, under which the device allowed the smartphone to use the captured image of the urine test strip and Color-Board. The performance of the device was not impacted by the dirty substances within the supported conditions.

Precision:
See Minuteful - kidney test summary (K210069).

Interference:
See Minuteful - kidney test summary (K210069).

Linearity:
See Minuteful - kidney test summary (K210069).

Stability:
See Minuteful - kidney test summary (K210069).

Clinical Performance Testing:

Method Comparison:
See Minuteful - kidney test summary (K210069).

Conclusion:

The modified Minuteful - kidney test is substantially equivalent to the predicate device Minuteful - kidney test cleared in K210069.