July 6, 2022

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

Re: K210069
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: April 13, 2022
Received: April 14, 2022

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,

Marianela Perez-Torres, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210069

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
K210069

Submitter:

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Contact Person: Ron Zohar

Date Prepared: April 13, 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
YD Diagnostics Corp.	URiSCAN Optima urine chemistry test system	K141874

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 is provided as a kit that comprises 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 VIII.I: Comparison between Minuteful - kidney test and YD Diagnostics Corp. URiSCAN Optima urine chemistry test system

Feature	Minuteful - kidney test	YD Diagnostics Corp. URiSCAN Optima (K141874)
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.	The URiSCAN Optima urine chemistry test system consists of URiSCAN Optima Urine analyzer and URiSCAN 2 ACR Urine strips. The intended use of the URiSCAN Optima Urine analyzer is to read the color change on the test pads found on the URiSCAN 2ACR Urine strips and to display and print the results. The intended use of the URiSCAN 2ACR Urine strips is for the in vitro semi quantitative measurement of the following parameters: Albumin Creatinine ACR (Albumin Creatinine Ratio) These measurements are useful in the evaluation of renal, urinary and metabolic disorders. URiSCAN Optima urine chemistry test system is intended for prescription use only, in clinical laboratory and in point-of-care setting.
Test Specimen	Urine	Urine
Detection Methodology	Reflectance photometry	Reflectance photometry

Detection Device	Photosensitive diode	Photosensitive diode
Strips	URiSCAN 2ACR urine strips (K141874)	URiSCAN 2ACR urine strips (K141874)
Analytes	albumin, creatinine	albumin, creatinine
Power Source	Not Applicable	URiSCAN Optima: DC 12V, 3.5A, 42VA AC/DC Adaptor: AC 100-240 V, 50/60 Hz, 1.2 A
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 with an EMR.	Bi-directional RS 232C interface High-speed thermal printer (203 dpi), barcode reader
Available languages on screen	English	English, German, Italian, Russian, Spanish, Portuguese, Korean, and Chinese
Measuring Cycle/Incubation Time	75 seconds	Routine test mode – 100 seconds Quick test mode – 6 seconds
Throughput	Not Applicable	36 tests/hour
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.	Not Applicable

Dimensions	187mm (W) x 143.6mm (L) x 24.6mm (H)	210mm (W) x 240mm (L) x 90mm (H)
Weight	0.125 kg	0.97kg

Summary of Performance Data:

Healthy.io conducted both bench and clinical studies to test the accuracy of the Minuteful - kidney test and its agreement with its predicate device. These analytical and clinical performance studies are summarized below.

Analytical Performance Testing:

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

Precision. This study consisted of two separate studies: 1) Repeatability and 2) Reproducibility. The precision studies were designed and executed in accordance with guidance provided by the Clinical and Laboratory Standards Institute (CLSI) document *EP05-A3 - Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.*

- **Repeatability.** The Minuteful - kidney test recorded **an exact match of 100%** during the course of the study.

- **Reproducibility.** The Minuteful - kidney test recorded **an exact match of 100%** during the course of the study. .

Interference. Testing of potential interfering substances with the Minuteful - kidney test was designed and executed in accordance with guidance provided by the Clinical and Laboratory Standards Institute (CLSI) document *EP07: Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition and CLSI EP37: Supplemental Tables for Interference Testing in Clinical Chemistry – First Edition.*

Limit of Detection. 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.*

Linearity. The linearity study of the Minuteful - kidney test was designed and executed in accordance with guidance provided by the Clinical and Laboratory Standards Institute (CLSI) document *EP6-A - Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*.

- The Minuteful - kidney test measured every level of albumin, creatinine and ACR at **an exact match of 100%.**

Stability. The stability experiment was designed to evaluate the ability of the Minuteful - kidney test to provide accurate measurements after exposure to environmental conditions (e.g.

temperature, humidity and vibration), which are designed to simulate aging and transportation conditions. This experiment was designed according to multiple International Electrotechnical Commission standards, *IEC TR 60721-4-1:2001+A1:-3, Class 2K2* and *IEC TR 60721-4-1:2001+A1:-3, Class 2M3*. The Minuteful - kidney test kits passed all tests and were not impacted by exposure to the different environmental conditions, demonstrating stability.

Clinical Performance Testing:

Method Comparison. The Method Comparison studies were conducted in accordance with Good Clinical Practice (GCP), according to 21 CFR Part 50, 54, 56, 812, ISO 14155-1/2 and relevant local and national regulations (IRB committee). In addition, the Method Comparison studies complied with CLSI EP09c: Method Comparison and Bias Estimation Using Patient Samples; Approved Guidelines – Third Edition. The objective of the Method Comparison studies was to evaluate the accuracy and usability performance of the Minuteful - kidney test in the hands of the lay user.

Study Design
More than 450 subjects were recruited to the clinical trials based on their ability to provide a urine sample and comfortably complete tasks using a smartphone. Each urine sample was tested by a lay user on the Minuteful - kidney test app, and then transferred to a professional user to conduct the test on the URiSCAN Optima Urine Analyzer. The professional user was blinded to the results of the lay user until after they had completed the test using the URiSCAN device.

Study Results - Accuracy
Results from subjects in the clinical trials were analyzed to show an exact agreement when compared to the comparator device. The **exact albumin-creatinine ratio agreement is 92.7%,** with an **overall ±1 color block of 100%**. Per analyte, the exact agreement for **albumin** is **92.1%** and for **creatinine 88.2%**, with **both overall ±1 color block of 100%**. The results show that the Minuteful - kidney test measurements are substantially equivalent to the measurements taken by the comparator device.

Study Results - Usability
100% of subjects were able to complete the study on the first attempt, with no usability issues.

Conclusions:

The clinical and analytical performance study results demonstrate that the Minuteful - kidney test is substantially equivalent to the predicate device URiSCAN Optima Urine Analyzer (K141874).