

K210069 Minute!ul - kidney testJul 6, 2022
541 days to decisionK210069 · Product code: JIR · Chemistry
Source: <https://www.510kdatabase.net/k210069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator Method, Protein Or Albumin (urinary, Non-quant.) (JIR)
Date received	Jan 11, 2021
Decision date	Jul 6, 2022
Days to decision	541 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Healthy.io, Ltd.
Location	Tel Aviv, IL
Contact	Ron Zohar
510(k) history	4 submissions · 4 cleared · 2018-2023

CLINICAL EVIDENCE - NCT04626271**Evaluation of the Accuracy and Usability of the ACR | U.S. Urine Analysis Test System in the Lay User Hands**

Status	Completed
Enrollment	250 patients (actual)
Study sites	2 sites
Condition studied	Albuminuria
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 25, 2020
Sponsor	Healthy.io Ltd. (Industry)

Primary outcome

Accuracy Evaluation: The Degree of Agreement (%) of the ACR | U.S. Urine Analysis Test System as Compared to the Comparator Device

Secondary outcome

Usability Evaluation: User Performance Analysis

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04626271