

K222921 Minuteful-kidney testSep 8, 2023
347 days to decisionK222921 · Product code: **JIR** · Chemistry
Source: <https://www.510kdatabase.net/k222921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator Method, Protein Or Albumin (urinary, Non-quant.) (JIR)
Date received	Sep 26, 2022
Decision date	Sep 8, 2023
Days to decision	347 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222921/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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