CLEARED

K203245 Bladder EpiCheck DNA extraction kit, NX899090-01C, Bladder EpiCheck test kit, NX899090-02C, Bladder EpiCheck Software, NX899090-03C

May 4, 2023
912 days to decision

K203245 · Product code: **MMW** · Medical Genetics
Source: https://www.510kdatabase.net/k203245/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Tumor Marker, Monitoring, Bladder (MMW)
Date received	Nov 3, 2020
Decision date	May 4, 2023
Days to decision	912 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nucleix , Ltd.**
Location	Rehovot, IL
Contact	Shmulik Adler
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT02647112

Utility of Bladder EpiCheck for Detection of Recurrent Urothelial Carcinoma

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	1050 patients (actual)
Study sites	6 sites
Condition studied	Bladder Cancer
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Single blind
Completion date	Dec 1, 2020
Sponsor	Nucleix Ltd. (Industry)

Primary outcome

Sensitivity (the proportion of positives that are correctly identified as such by the gold standard)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02647112