

K250911 MOSkin Radiation Measurement SystemOct 17, 2025
205 days to decisionK250911 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k250911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 26, 2025
Decision date	Oct 17, 2025
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Electrogenics Labs, Ltd.
Location	North Sydney, AU
Contact	David Rundell
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026