

K241232 Galen™ Second Read™Jan 24, 2025
267 days to decisionK241232 · Product code: **QPN** · Pathology
Source: <https://www.510kdatabase.net/k241232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software Algorithm Device To Assist Users In Digital Pathology (QPN)
Date received	May 2, 2024
Decision date	Jan 24, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ibex Medical Analytics , Ltd.
Location	Tel Aviv, IL
Contact	Yael Liebes Peer
510(k) history	1 submissions · 1 cleared · 2025-2025

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