

K252431 Elecsys CalcitoninApr 24, 2026
266 days to decisionK252431 · Product code: **JKR** · Chemistry
Source: <https://www.510kdatabase.net/k252431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Calcitonin (JKR)
Date received	Aug 1, 2025
Decision date	Apr 24, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics GmbH
Location	Mannheim, DE
Contact	Eva Jad
510(k) history	5 submissions · 5 cleared · 1998-2026

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