

K252327 CMORE® CT SystemNov 12, 2025
110 days to decisionK252327 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k252327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jul 25, 2025
Decision date	Nov 12, 2025
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CMORE® CT System Navigated Instruments

APPLICANT

Company	Icotec AG
Location	Altstaetten, SE
Contact	Vanessa Faessler
510(k) history	16 submissions · 16 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Michael Coladonato

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

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