FDA 510(k) Premarket Notification

K252327 CMORE® CT System

CLEARED

Nov 12, 2025
110 days to decision

K252327 · 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