

K250928 OmniTom Elite with PCDSep 8, 2025
164 days to decisionK250928 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k250928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 28, 2025
Decision date	Sep 8, 2025
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurologica Corporation
Location	Danvers, MA, US
Contact	Ninad Gujar
510(k) history	8 submissions · 8 cleared · 2005-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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