

K223447 OmniTom EliteJun 1, 2023
198 days to decisionK223447 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k223447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 15, 2022
Decision date	Jun 1, 2023
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurologica Corporation, A Subsidiary of Samsung
Location	Danvers, MA, US
Contact	Ninad Gujar
510(k) history	2 submissions · 2 cleared · 2023-2025

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