

K211711 OmniTom EliteFeb 25, 2022
267 days to decisionK211711 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k211711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jun 3, 2021
Decision date	Feb 25, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurologica Corporation, A Subsidiary of Samsung Electronics
Location	Danvers, MA, US
Contact	Ninad Gujar
510(k) history	4 submissions · 4 cleared · 2017-2022

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