

K242811 BodyTom 64Mar 14, 2025
177 days to decisionK242811 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k242811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 18, 2024
Decision date	Mar 14, 2025
Days to decision	177 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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