

K213649 BodyTom 64Apr 29, 2022
161 days to decisionK213649 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k213649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 19, 2021
Decision date	Apr 29, 2022
Days to decision	161 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/k213649/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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