

K253450 BodyTom Elite (NL4000)

Jul 28, 2026
299 days to decision

K253450 · Product code: JAK · Radiology
Source: <https://www.510kdatabase.net/k253450/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Oct 2, 2025
Decision date	Jul 28, 2026
Days to decision	299 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	NeuroLogica Corp., a Samsung Company
Location	Danvers, MA, US
Contact	Ninad Gujar
510(k) history	1 submissions · 1 cleared · 2026-2026