

K251061 NAEOTOM Alpha.Peak/NAEOTOM AlphaJul 28, 2025
115 days to decisionK251061 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k251061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 4, 2025
Decision date	Jul 28, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NAEOTOM Alpha.Pro; NAEOTOM Alpha.Prime

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Tabitha Estes
510(k) history	778 submissions · 778 cleared · 1980-2026

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