

K213942 EsteyaJan 11, 2022
25 days to decisionK213942 · Product code: **JAD** · Radiology
Source: <https://www.510kdatabase.net/k213942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Dec 17, 2021
Decision date	Jan 11, 2022
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nucletron B.V.
Location	Rice Lake, WI, US
Contact	Kiran Jose
510(k) history	11 submissions · 11 cleared · 2013-2025

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