

K213465 CardioGrapheDec 2, 2022
400 days to decisionK213465 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k213465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Oct 28, 2021
Decision date	Dec 2, 2022
Days to decision	400 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arineta , Ltd.
Location	Caesarea, IL
Contact	Tanya Shalem
510(k) history	5 submissions · 5 cleared · 2016-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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