

K210085 HealthCCSngSep 15, 2021
245 days to decisionK210085 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k210085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jan 13, 2021
Decision date	Sep 15, 2021
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zebra Medical Vision, Ltd.
Location	Sefayim, IL
Contact	Shlomit Cymbalista
510(k) history	9 submissions · 9 cleared · 2018-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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