

K212067 Deep Learning Image ReconstructionSep 17, 2021
77 days to decisionK212067 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k212067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 2, 2021
Decision date	Sep 17, 2021
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare Japan Corporation
Location	Hino-Shi, Tokyo, JP
Contact	Katelyn Rowley
510(k) history	10 submissions · 10 cleared · 2011-2026

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