

**K220961 Deep Learning Image Reconstruction**Jul 29, 2022  
119 days to decisionK220961 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k220961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 1, 2022
Decision date	Jul 29, 2022
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Healthcare Japan Corporation</b>
Location	Hino-Shi, Tokyo, JP
Contact	Wang Xing
510(k) history	10 submissions · 10 cleared · 2011-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220961/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026