

**K193170 Deep Learning Image Reconstruction**Dec 13, 2019  
28 days to decisionK193170 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k193170/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 15, 2019
Decision date	Dec 13, 2019
Days to decision	28 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	Tomohiro Ito
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/k193170/> 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