

**K123596 OPTIMA CT520**Feb 8, 2013  
79 days to decisionK123596 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k123596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 21, 2012
Decision date	Feb 8, 2013
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Hangwei Medical Systems Co., Ltd.</b>
Location	Beijing, CN
Contact	HELEN PENG
510(k) history	10 submissions · 10 cleared · 2011-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123596/> 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 27, 2026