

**K132410 DISCOVERY CT 590 RT, OPTIMA CT 580, OPTIMA CT 580 RT, OPTIMA CT 580 W**Jan 17, 2014  
168 days to decisionK132410 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k132410/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Aug 2, 2013
Decision date	Jan 17, 2014
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems, LLC</b>
Location	Waukesha, WI, US
Contact	HELEN PENG
Website	<a href="https://www.gehealthcare.com">https://www.gehealthcare.com</a>
510(k) history	104 submissions · 104 cleared · 2003-2026

GE Medical Systems, LLC is a medical device manufacturer based in Waukesha, US. The company specializes in Radiology devices and solutions. GE Medical Systems has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely on Radiology devices, with a clearance history spanning from 2003 to 2026. The latest clearance in 2026 demonstrates active regulatory engagement within the past two years. Recent cleared devices include advanced imaging systems such as the Photonova Spectra series, SIGNA™ product line, AIR Recon DL, Revolution Vibe...