

**K140235 XGEO GR40CW**May 15, 2014  
105 days to decisionK140235 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k140235/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jan 30, 2014
Decision date	May 15, 2014
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Samsung Electronics Co., Ltd.</b>
Location	Echo, OR, US
Contact	JEONGPYO HONG
Website	<a href="http://www.samsung.com">http://www.samsung.com</a>
510(k) history	40 submissions · 39 cleared · 2013-2024

Samsung Electronics Co., Ltd. is a South Korean multinational electronics corporation headquartered in Suwon. The company maintains a regulatory presence in the United States through its Echo, US location. Samsung has submitted total applications for FDA 510(k) clearance and received clearances. The company's regulatory focus centers on Radiology devices, which represent 83% of submissions. Samsung's FDA 510(k) clearance history spans from 2013 to 2024, with recent clearances demonstrating continued regulatory activity in medical imaging and cardiovascular monitoring tech...

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