

**K160997 GC85A**Jul 6, 2016  
86 days to decisionK160997 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k160997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Apr 11, 2016
Decision date	Jul 6, 2016
Days to decision	86 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	CHULSIN KIM
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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