FDA 510(k) Premarket Notification

K172229 GC85A

CLEARED

Nov 22, 2017
120 days to decision

K172229 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k172229/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Jul 25, 2017
Decision date	Nov 22, 2017
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Samsung Electronics Co., Ltd.**
Location	Echo, OR, US
Contact	Jaesang NOH
Website	http://www.samsung.com
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...