FDA 510(k) Premarket Notification

K201168 ECG Monitor App

CLEARED

Aug 4, 2020
95 days to decision

K201168 · Product code: **QDA** · Cardiovascular
Source: https://www.510kdatabase.net/k201168/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	May 1, 2020
Decision date	Aug 4, 2020
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Samsung Electronics Co., Ltd.**
Location	Echo, OR, US
Contact	Taejong Jay Yang
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...