FDA 510(k) Premarket Notification

K213452 GEMS-H

CLEARED

Apr 21, 2022
177 days to decision

K213452 · Product code: **PHL** · Neurology
Source: https://www.510kdatabase.net/k213452/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Exoskeleton (PHL)
Date received	Oct 26, 2021
Decision date	Apr 21, 2022
Days to decision	177 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	Minhyung Lee
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...

REGULATORY CONSULTANT

Consulting firm	**Mdlab, Inc.**
Contact	Kyoungju Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT04285060

Safety and Efficacy of Samsung GEMS-H Device Training in Sub-Acute and Chronic Stroke

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	100 patients (estimated)
Study sites	1 site
Condition studied	Stroke; Chronic Stroke
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 1, 2021
Sponsor	Samsung Electronics (Industry)

Primary outcome

Incidence of device related adverse events

Secondary outcome

6 Minute Walk Test (6MWT)