FDA 510(k) Premarket Notification

K221438 WHILL Model F

CLEARED

Jun 7, 2022
21 days to decision

K221438 · Product code: **ITI** · Physical Medicine
Source: https://www.510kdatabase.net/k221438/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wheelchair, Powered (ITI)
Date received	May 17, 2022
Decision date	Jun 7, 2022
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Whill, Inc.**
Location	San Carlos, CA, US
Contact	Tsuyoshi Iriyama
510(k) history	4 submissions · 4 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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