FDA 510(k) Premarket Notification

CLEARED

K213655 HiTop® (Models: HiToP®4touch, HiToP®2touch, HiToP®1touch)

Jan 17, 2023
424 days to decision

K213655 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k213655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Nov 19, 2021
Decision date	Jan 17, 2023
Days to decision	424 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hilltek, LLC**
Location	Anaheim, CA, US
Contact	Mohammadali Nezakati
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Bhoomika Joyappa

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