FDA 510(k) Premarket Notification

K222912 c1Trac

CLEARED

May 16, 2023
232 days to decision

K222912 · Product code: **ITH** · Physical Medicine
Source: https://www.510kdatabase.net/k222912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Equipment, Traction, Powered (ITH)
Date received	Sep 26, 2022
Decision date	May 16, 2023
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Medizinsysteme GmbH**
Location	Neu-Ulm, DE
Contact	Ute Hauss
510(k) history	13 submissions · 13 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	**Quality and Regulatory Services**
Contact	Scott Blood

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