

K222912 c1TracMay 16, 2023
232 days to decisionK222912 · Product code: **ITH** · Physical MedicineSource: <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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222912/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026