

K243366 DRX9000C-SL Cervical Spinal Decompression SystemJun 18, 2025
233 days to decisionK243366 · Product code: **ITH** · Physical Medicine
Source: <https://www.510kdatabase.net/k243366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Equipment, Traction, Powered (ITH)
Date received	Oct 28, 2024
Decision date	Jun 18, 2025
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Excite Medical of Tampa Bay, LLC
Location	Tampa, FL, US
Contact	Saleem Musallam
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Cofactor Technologies, Inc.
Contact	Jon Werner

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/k243366/> 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