

**K243775 True Non-Surgical Spinal Decompression System  
(DRX9000-SL)**Jul 18, 2025  
221 days to decisionK243775 · Product code: ITH · Physical Medicine  
Source: <https://www.510kdatabase.net/k243775/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Equipment, Traction, Powered (ITH)
Date received	Dec 9, 2024
Decision date	Jul 18, 2025
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Cofactor Technologies, Inc.</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243775/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026