FDA 510(k) Premarket Notification

CLEARED

K250817 Coretech Compression System (Coretech RHB3003)

Aug 8, 2025
143 days to decision

K250817 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k250817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Mar 18, 2025
Decision date	Aug 8, 2025
Days to decision	143 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vive Health, LLC**
Location	Naples, FL, US
Contact	Joe Fleming
Website	https://www.vivehealth.com
510(k) history	2 submissions · 2 cleared · 2025-2025

Vive Health, LLC is an online medical equipment and supplies retailer offering a broad range of home health devices and mobility aids. The company operates with a manufacturing facility in Naples, US. Vive Health has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's cleared devices span cardiovascular and physical medicine categories, with clearances issued in 2025. This recent regulatory activity demonstrates active engagement in the FDA 510(k) clearance process. The company's product portfolio includes power wheel...

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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