

K253555 Flexitouch® Plus Advanced Pneumatic Compression System

Jul 31, 2026
259 days to decision

K253555 · Product code: JOW · Cardiovascular
Source: <https://www.510kdatabase.net/k253555/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Nov 14, 2025
Decision date	Jul 31, 2026
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tactile Medical
Location	Minneapolis, MN, US
Contact	Sunday Hoy
Website	https://tactilemedical.com
510(k) history	3 submissions · 3 cleared · 2024-2026

Tactile Medical develops at-home therapy devices for chronic swelling conditions. The company specializes in pneumatic compression systems treating lymphedema and chronic venous insufficiency. Headquartered in Minneapolis, Minnesota, Tactile Medical combines innovative devices with personalized patient support and reimbursement expertise. The company has received FDA 510(k) clearances from total submissions. Tactile Medical’s cleared devices span anesthesiology and cardiovascular categories, with first clearance in 2024 and most recent clearance in 2026. The company remai...