FDA 510(k) Premarket Notification

CLEARED

K250756 Pression Wave PRO External Counter-Pulsation System

Dec 22, 2025
285 days to decision

K250756 · Product code: **DRN** · Cardiovascular
Source: https://www.510kdatabase.net/k250756/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Mar 12, 2025
Decision date	Dec 22, 2025
Days to decision	285 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pression, Inc.**
Location	Coatesville, PA, US
Contact	Adam Salamon
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Broderick Regulatory Consulting, LLC**
Contact	Julie Broderick

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