FDA 510(k) Premarket Notification

CLEARED

K250225 Bolt Intravascular Lithotripsy (IVL) System

Mar 25, 2025
57 days to decision

K250225 · Product code: **PPN** · Cardiovascular
Source: https://www.510kdatabase.net/k250225/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Catheter, Ultrasound (PPN)
Date received	Jan 27, 2025
Decision date	Mar 25, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bolt Medical, Inc.**
Location	Carlsbad, CA, US
Contact	Stephanie Onstot
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT05662787

BOLT Lithotripsy RESTORE ATK Trial

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	97 patients (actual)
Study sites	11 sites
Condition studied	Peripheral Arterial Disease; Peripheral Vascular Diseases
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 30, 2024
Sponsor	Bolt Medical (Industry)

Primary outcome

Primary Effectiveness Endpoint

Secondary outcome

Freedom from Major Adverse Events (MAEs) within 6 months.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05662787