

K243795 pREBOA-PRO CatheterSep 5, 2025
269 days to decisionK243795 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k243795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 10, 2024
Decision date	Sep 5, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prytime Medical Devices, Inc.
Location	Boerne, TX, US
Contact	Brian Young
510(k) history	5 submissions · 5 cleared · 2017-2025

CLINICAL EVIDENCE - NCT00459160**A Comparison of Two Target Mean Arterial Pressures in the Resuscitation of Hypotensive Trauma Patients**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	271 patients (estimated)
Study sites	1 site
Condition studied	Hemorrhagic Shock; Trauma; Wounds, Penetrating; Shock, Traumatic; Multiple Trauma
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jul 1, 2011
Sponsor	Baylor College of Medicine (Other)

Primary outcome

30 day survival

Secondary outcome

Sequential Organ Failure Assessment (SOFA) score

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT00459160