

K250974 Bio Arterial Deluxe (IC-BAP-DX)Dec 12, 2025
256 days to decisionK250974 · Product code: **JOW** · CardiovascularSource: <https://www.510kdatabase.net/k250974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Mar 31, 2025
Decision date	Dec 12, 2025
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bio Compression Systems, Inc.
Location	Moonachie, NJ, US
Contact	Marc Somelofski
510(k) history	15 submissions · 15 cleared · 1996-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250974/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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