

K252373 BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve TechnologyDec 16, 2025
139 days to decisionK252373 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k252373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Jul 30, 2025
Decision date	Dec 16, 2025
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioFlo PICC with ENDEXO Technology and PASV Valve Technology; BioFlo PICC with ENDEXO Technology; BioFlo Midline Catheter; Xcela Power Injectable PICC; Xcela PICC with PASV Valve Technology; Xcela Hybrid PICC with PASV Valve Technology

APPLICANT

Company	Spectrum Vascular
Location	White Plains, NY, US
Contact	Sharon Klugewicz
510(k) history	4 submissions · 4 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252373/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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