

**K243458 HydroPICC 4Fr Single Lumen Marked catheter, 130 cm guidewire - Basic Kit (70001301)**

Aug 1, 2025  
266 days to decision

K243458 · Product code: **LJS** · General Hospital  
Source: <https://www.510kdatabase.net/k243458/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Nov 8, 2024
Decision date	Aug 1, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HydroPICC 4Fr Single Lumen Marked catheter, 70 cm guidewire - Basic Kit (70001302); HydroPICC 4Fr Single Lumen Marked catheter - Maximal Barrier kit (70001304); HydroPICC 5Fr Dual Lumen Marked catheter, 130 cm guidewire - Basic Kit (70002301); HydroPICC 5Fr Dual Lumen Marked catheter, 70 cm guidewire - Basic Kit (70002302); HydroPICC 5Fr Dual Lumen Marked catheter - Maximal Barrier kit (70002304); Hydr

**APPLICANT**

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Company	<b>Access Vascular, Inc.</b>
Location	Bedford, MA, US
Contact	Brian Hanley
510(k) history	9 submissions · 9 cleared · 2018-2025

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