

**K240589 Micropuncture Introducer Sets**Mar 25, 2024  
24 days to decisionK240589 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k240589/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 1, 2024
Decision date	Mar 25, 2024
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Micropuncture Pedal Access Sets

**APPLICANT**

---

Company	<b>Cook, Medical</b>
Location	Bloomington, IN, US
Contact	David Lehr
510(k) history	1 submissions · 1 cleared · 2024-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240589/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026