

**K203459 SafeCross Transseptal Puncture and Introducer (TSP/I) System**Jul 6, 2021  
224 days to decisionK203459 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k203459/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 24, 2020
Decision date	Jul 6, 2021
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>East End Medical I, LLC</b>
Location	Sunrise, FL, US
Contact	Brij Maini
510(k) history	2 submissions · 2 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mandell Horwitz Consultants, LLC</b>
Contact	Diane Horwitz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203459/> 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 26, 2026