

**K261950 Health Line Tearaway Introducer**Jun 22, 2026  
12 days to decisionK261950 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k261950/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 10, 2026
Decision date	Jun 22, 2026
Days to decision	12 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Health Line International Corporation</b>
Location	Clearfield, UT, US
Contact	Aaron Faulkner
510(k) history	12 submissions · 10 cleared · 2006-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261950/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 11, 2026