

**K152090 Reprocessed Steerable Introducer**Mar 23, 2016  
240 days to decisionK152090 · Product code: **PNE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152090/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Catheter Introducer (PNE)
Date received	Jul 27, 2015
Decision date	Mar 23, 2016
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sterilmed, Inc.</b>
Location	Plymouth, MN, US
Contact	Patricia Kaufman
510(k) history	64 submissions · 64 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152090/> 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 May 19, 2026