

**K153778 Nester Embolization Coils, Tornado Embolization Coils**May 19, 2016  
140 days to decisionK153778 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153778/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Dec 31, 2015
Decision date	May 19, 2016
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	David Lehr
510(k) history	175 submissions · 153 cleared · 2006-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153778/>; 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 June 3, 2026