

**K163353 Needle&apos;s Eye Snare Retrieval Set - 54cm**Jul 11, 2017  
223 days to decisionK163353 · Product code: **DXE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163353/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Embolectomy (DXE)
Date received	Nov 30, 2016
Decision date	Jul 11, 2017
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163353/> 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 1, 2026