

**K172527 Amplatz Renal Dilator Set, Catheter for Use with Amplatz Renal Dilator Set, Amplatz Dilator, Amplatz Renal Introducer, Amplatz Radiopaque TFE Sheath, Clear Amplatz Sheath with Radiopaque Stripe**Oct 19, 2017  
59 days to decisionK172527 · Product code: LJE · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k172527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Aug 21, 2017
Decision date	Oct 19, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Rebecca Odulio (Li-chun Liu)
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/k172527/> 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 31, 2026