

**K181735 Percutaneous Neonatal Pigtail Nephrostomy Set,  
Pediatric Nephrostomy Stent Set**

Mar 27, 2019  
268 days to decision

K181735 · Product code: **LJE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k181735/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jul 2, 2018
Decision date	Mar 27, 2019
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Paul Meyer
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/k181735/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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