

**K191498 Cook-Cope Loop Nephrostomy Set, Ultrathane Nephrostomy Set with Mac-Loc, Ultrathane Suprapubic Set with Mac-Loc**Jan 29, 2020  
238 days to decisionK191498 · Product code: **LJE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k191498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jun 5, 2019
Decision date	Jan 29, 2020
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Carly Powell
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/k191498/>; 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 14, 2026