

**K211911 Kolibri Percutaneous Nephrostomy Catheters, Kolibri Percutaneous Nephrostomy Kits, Kolibri Direct Puncture Sets**Mar 10, 2022  
262 days to decisionK211911 · Product code: **LJE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k211911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jun 21, 2021
Decision date	Mar 10, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coloplast Corp.</b>
Location	Marietta, GA, US
Contact	Angela Kilian
510(k) history	54 submissions · 47 cleared · 1985-2025

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