

K171601 Ultraxx Nephrostomy Balloon CatheterFeb 23, 2018
267 days to decisionK171601 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k171601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jun 1, 2017
Decision date	Feb 23, 2018
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Minjin Choi
510(k) history	175 submissions · 153 cleared · 2006-2024

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