

K181713 Ultraxx Nephrostomy Balloon Catheter SetAug 17, 2018
50 days to decisionK181713 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jun 28, 2018
Decision date	Aug 17, 2018
Days to decision	50 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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