

**K915209 MALECOT-NEPHROSTOMY TAMPONADE CATHETER**Nov 10, 1992  
358 days to decisionK915209 · Product code: **LJE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k915209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Nov 18, 1991
Decision date	Nov 10, 1992
Days to decision	358 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cook Urological, Inc.</b>
Location	Spencer, IN, US
Contact	MICHELLE YOUNG
510(k) history	104 submissions · 102 cleared · 1986-2011

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