

**K891406 BALLOON (NEPHROSTOMY TRACT) DILATION
CATHETER SET**Apr 7, 1989
24 days to decisionK891406 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k891406/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Mar 14, 1989
Decision date	Apr 7, 1989
Days to decision	24 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891406/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026