

**K925161 NORTEC STERILE WATER FOR CATHETER BALLOON  
INFLATIO**Jul 21, 1993  
281 days to decisionK925161 · Product code: **KNY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k925161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Catheter, G-u (KNY)
Date received	Oct 13, 1992
Decision date	Jul 21, 1993
Days to decision	281 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>North American Sterilization &amp; Packaging Co.</b>
Location	Sparta, NJ, US
Contact	CHARLES E MEISCH
510(k) history	16 submissions · 16 cleared · 1989-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k925161/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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