

**K120127 SWAN VALLEY MEDICAL TRANURETHRAL  
SUPRAPUBIC ENDO-CYSTOSTOMY (T-SPEC) SURGICAL  
SYSTEM**Oct 26, 2012  
283 days to decisionK120127 · Product code: **KOB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k120127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Suprapubic (and Accessories) (KOB)
Date received	Jan 17, 2012
Decision date	Oct 26, 2012
Days to decision	283 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Swan Valley Medical, Incorporated</b>
Location	Golden, CO, US
Contact	KEVIN RANDALL
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120127/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 15, 2026