

**K970443 HOLLISTER RETRACTED PENIS POUCH**Feb 25, 1997  
20 days to decisionK970443 · Product code: **EXI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Paste-on For Incontinence, Sterile (EXI)
Date received	Feb 5, 1997
Decision date	Feb 25, 1997
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hollister, Inc.</b>
Location	Mchenry, IL, US
Contact	JOSEPH S TOKARZ
510(k) history	85 submissions · 78 cleared · 1977-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970443/> 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 May 22, 2026