

**K110214 DIRECTVISION CATHETER, UNCOATED**May 27, 2011  
122 days to decisionK110214 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k110214/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jan 25, 2011
Decision date	May 27, 2011
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Percuision</b>
Location	Ashland, MA, US
Contact	FIDES MALDONADO
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110214/> 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 19, 2026