

**K181346 CystoSure Plus Catheter**Aug 6, 2018  
77 days to decisionK181346 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k181346/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	May 21, 2018
Decision date	Aug 6, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Emmy Medical, LLC</b>
Location	Holliston, MA, US
Contact	Ronald Adams
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181346/> 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 30, 2026