

**K062112 SUNMED FOLEY CATHETERS**Jun 4, 2007  
315 days to decisionK062112 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k062112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 24, 2006
Decision date	Jun 4, 2007
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sunmed, Inc.</b>
Location	Clearwater, FL, US
Contact	ARTHUR WARD
510(k) history	4 submissions · 4 cleared · 1993-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062112/> 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 21, 2026