

**K061009 PATHWAY BALLOON EXPANDABLE URETERAL  
ACCESS SHEATH, MODEL BEUS**May 2, 2006  
20 days to decisionK061009 · Product code: **EZN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k061009/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Apr 12, 2006
Decision date	May 2, 2006
Days to decision	20 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Onset Medical Corporation</b>
Location	Mission Viejo, CA, US
Contact	ALBERT REGO
510(k) history	8 submissions · 8 cleared · 2005-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061009/>; 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 3, 2026