

**K140561 AXIOS STENT AND DELIVERY SYSTEM (WITH 10MM X 10MM STENT) AXIOS STENT AND DELIVERY SYSTEM (WITH 15MM X 10MM STENT)**Apr 23, 2014  
49 days to decisionK140561 · Product code: **PCU** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k140561/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pancreatic Stent, Covered, Metallic, Removable (PCU)
Date received	Mar 5, 2014
Decision date	Apr 23, 2014
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xlumena, Inc.</b>
Location	Mountain View, CA, US
Contact	JANE BEGGS
510(k) history	2 submissions · 1 cleared · 2013-2014

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