

**K151084 Well Lead Ureteral Access Sheath**Jan 7, 2016  
260 days to decisionK151084 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k151084/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Apr 22, 2015
Decision date	Jan 7, 2016
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Well Lead Medical Co., Ltd.</b>
Location	Apollo Beach, FL, US
Contact	HUANG KAI GEN
510(k) history	17 submissions · 17 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151084/> 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 25, 2026