

**K140482 MANDREL GUIDEWIRE**Apr 8, 2014  
41 days to decisionK140482 · Product code: **OCY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k140482/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	Feb 26, 2014
Decision date	Apr 8, 2014
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lake Region Medical</b>
Location	Chaska, MN, US
Contact	MATHEW PEXA
510(k) history	16 submissions · 16 cleared · 2008-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140482/> 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 14, 2026