

**K151471 Radifocus Glidewire Endoscopic Wire**Sep 17, 2015  
108 days to decisionK151471 · Product code: **OCY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k151471/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	Jun 1, 2015
Decision date	Sep 17, 2015
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Medical Corporation</b>
Location	Elkton, MD, US
Contact	Phebe Varghese
510(k) history	14 submissions · 14 cleared · 2011-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151471/> 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 26, 2026