

**K140295 GIS ENDOSCOPIC OPTICAL LENS**Jul 24, 2014  
168 days to decisionK140295 · Product code: **FDS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k140295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Feb 6, 2014
Decision date	Jul 24, 2014
Days to decision	168 days
Third-party review	No

**APPLICANT**

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Company	<b>Gi Scientific, LLC</b>
Location	Newbury, NH, US
Contact	MICHELE LUCEY
510(k) history	2 submissions · 2 cleared · 2014-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140295/>; 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 25, 2026