

**K051533 I-STOP**Aug 11, 2005  
63 days to decisionK051533 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k051533/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jun 9, 2005
Decision date	Aug 11, 2005
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CI Medical</b>
Location	Sainte Foy Les Lyon, FR
Contact	VINCENT GORIA
510(k) history	2 submissions · 2 cleared · 2005-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051533/> 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 29, 2026