

**K013355 SPARC SLING SYSTEM**Oct 26, 2001  
16 days to decisionK013355 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k013355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Oct 10, 2001
Decision date	Oct 26, 2001
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Medical Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	GINGER S GLASER
510(k) history	72 submissions · 72 cleared · 1979-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013355/> 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