

**K053371 AMS MALE TRANSOBTURATOR SLING SYSTEM**Feb 3, 2006  
60 days to decisionK053371 · Product code: **OTM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k053371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, For Stress Urinary Incontinence, Male (OTM)
Date received	Dec 5, 2005
Decision date	Feb 3, 2006
Days to decision	60 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	FRANK B FREEDMAN
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/k053371/> 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