

**K051485 AMS PELVIC FLOOR REPAIR SYSTEM**Aug 3, 2005  
58 days to decisionK051485 · Product code: **OTO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k051485/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed (OTO)
Date received	Jun 6, 2005
Decision date	Aug 3, 2005
Days to decision	58 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	ELSA LINKE
510(k) history	72 submissions · 72 cleared · 1979-2013

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