

**K121612 ELEVATE PROLAPSE REPAIR SYSTEMS-APICAL  
NEEDLE PASSER SHEATH MODIFICATION**Jul 20, 2012  
49 days to decisionK121612 · Product code: **OTP** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k121612/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Jun 1, 2012
Decision date	Jul 20, 2012
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Medical Systems</b>
Location	Minnetonka, MN, US
Contact	NGOC LINH PHAM LATCHMAN
Website	<a href="http://www.varian.com">http://www.varian.com</a>
510(k) history	10 submissions · 10 cleared · 2008-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121612/> 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 6, 2026