

K112842 AMS ELEVATE PCOct 25, 2011
26 days to decisionK112842 · Product code: **OTP** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k112842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Pelvic Organ Prolapse, Transvaginally Placed (OTP)
Date received	Sep 29, 2011
Decision date	Oct 25, 2011
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems, Inc.
Location	Mchenry, IL, US
Contact	MATTHEW D STEPANEK
510(k) history	72 submissions · 72 cleared · 1979-2013

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