

K121805 AMS LARGE PORE POLYPROPYLENE MESHOct 16, 2012
119 days to decisionK121805 · Product code: **OTO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k121805/>**SUBMISSION DETAILS**

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 19, 2012
Decision date	Oct 16, 2012
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems
Location	Minnetonka, MN, US
Contact	RENEE MELLUM
Website	http://www.varian.com
510(k) history	10 submissions · 10 cleared · 2008-2014

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