

**K120327 VERTESSA**May 10, 2012  
98 days to decisionK120327 · Product code: **OTO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k120327/>**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	Feb 2, 2012
Decision date	May 10, 2012
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Caldera Medical, Inc.</b>
Location	Agoura Hills, CA, US
Contact	VICKI GAIL
510(k) history	22 submissions · 22 cleared · 2006-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120327/> 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 14, 2026