

**K150016 Vertessa Lite**Apr 6, 2015  
91 days to decisionK150016 · Product code: **OTO** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k150016/>**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	Jan 5, 2015
Decision date	Apr 6, 2015
Days to decision	91 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/k150016/> 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 May 14, 2026