

K123337 VERTESSA LITE 10 X 20CM, VERTESSA LITE 11 X 30CMFeb 21, 2013
113 days to decisionK123337 · Product code: **OTO** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k123337/>**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	Oct 31, 2012
Decision date	Feb 21, 2013
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Caldera Medical
Location	Agoura Hills, CA, US
Contact	VICKI GAIL
510(k) history	2 submissions · 2 cleared · 2013-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123337/>; Data sourced from FDA 510(k) public records (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. - Generated June 6, 2026