K123337 VERTESSA LITE 10 X 20CM, VERTESSA LITE 11 X 30CM

CLEARED

Feb 21, 2013
113 days to decision

K123337 · 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