FDA 510(k) Premarket Notification

K120327 VERTESSA

CLEARED

May 10, 2012
98 days to decision

K120327 · Product code: **OTO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k120327/

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	Feb 2, 2012
Decision date	May 10, 2012
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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