

**K132069 DESARA MESH, DESARA BLUE**Sep 23, 2013  
82 days to decisionK132069 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k132069/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jul 3, 2013
Decision date	Sep 23, 2013
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132069/> 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