

**K211975 Desara TV EZ 3.0 System, Desara Blue TV EZ 3.0 System, Desara TV EZ 2.7 System, Desara Blue TV EZ 2.7 System**Nov 10, 2021  
138 days to decisionK211975 · Product code: **OTN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k211975/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jun 25, 2021
Decision date	Nov 10, 2021
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	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/k211975/> 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 13, 2026