

K162201 Desara TV, Desara Blue TVJan 11, 2017
159 days to decisionK162201 · Product code: **OTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162201/>**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	Aug 5, 2016
Decision date	Jan 11, 2017
Days to decision	159 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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