

K191416 Desara One Single Incision Sling System, 1 PackFeb 7, 2020
255 days to decisionK191416 · Product code: **PAH** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k191416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-sling (PAH)
Date received	May 28, 2019
Decision date	Feb 7, 2020
Days to decision	255 days
Third-party review	No
Summary / Statement	Statement
Other names	Desara One Single Incision Sling System, 3 Pack

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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