

K172614 Caldera Medical Transobturator Helical Introducer, LeftMay 4, 2018
246 days to decisionK172614 · Product code: **PWJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation, Surgical Mesh, Urogynecologic, Stress Urinary Incontinence (PWJ)
Date received	Aug 31, 2017
Decision date	May 4, 2018
Days to decision	246 days
Third-party review	No
Summary / Statement	Statement
Other names	Caldera Medical Transobturator Helical Introducer, Right; Caldera Medical Transobturator Large Helical Introducer, Left; Caldera Medical Transobturator Large Helical Introducer, Right; Caldera Medical Transobturator Inside-Out Introducer, Left

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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