

**K242536 TauTona Pneumoperitoneum Assist Device (TPAD)**Oct 15, 2024  
50 days to decisionK242536 · Product code: **HIF** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k242536/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Aug 26, 2024
Decision date	Oct 15, 2024
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tautona Group</b>
Location	Redwood City, CA, US
Contact	Mike Blanchette
510(k) history	1 submissions · 1 cleared · 2024-2024

**CLINICAL EVIDENCE - NCT04392635****Device to Assist With Abdominal Access During Laparoscopic Surgery**

---

Status	Completed
Enrollment	31 patients (actual)
Study sites	1 site
Condition studied	Laparoscopic Surgery
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jun 17, 2024
Sponsor	Stanford University (Other)

**Primary outcome**

Surgeon Satisfaction Survey

**Secondary outcome**

Time From Incision for Veress Needle Insertion to Start of Insufflation

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04392635](https://clinicaltrials.gov/study/NCT04392635)