

**K243750 SimpleStitch Suturing System**Apr 17, 2025  
133 days to decisionK243750 · Product code: **OCW** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243750/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Dec 5, 2024
Decision date	Apr 17, 2025
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Envision Endoscopy</b>
Location	Waltham, MA, US
Contact	Azadeh Khanicheh
510(k) history	2 submissions · 2 cleared · 2024-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243750/> 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