

**K201696 ENSEAL X1 Tissue Sealer, Straight Jaw, 25 cm Shaft Length, ENSEAL X1 Tissue Sealer, Straight Jaw, 37 cm Shaft Length**Jan 22, 2021  
214 days to decisionK201696 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k201696/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 22, 2020
Decision date	Jan 22, 2021
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ethicon Endo-Surgery, LLC</b>
Location	Blue Ash, OH, US
Contact	Nathan Anderson
Website	<a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a>
510(k) history	69 submissions · 69 cleared · 2006-2026

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Ethicon Endo-Surgery, Inc.</b>
Contact	Kweku Biney

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201696/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026