

K201066 ENSEAL X1 Tissue Sealer, Curved Jaw, 25 cm Shaft Length, ENSEAL X1 Tissue Sealer, Curved Jaw, 37 cm Shaft Length, ENSEAL X1 Tissue Sealer, Curved Jaw, 45 cm Shaft LengthJan 22, 2021
275 days to decisionK201066 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k201066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 22, 2020
Decision date	Jan 22, 2021
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Ethicon Endo-Surgery, Inc.
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.netDevice record: <https://www.510kdatabase.net/k201066/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026