

K160554 Enseal X1 Large Jaw Tissue SealerSep 9, 2016
193 days to decisionK160554 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 29, 2016
Decision date	Sep 9, 2016
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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