

**K163548 ENSEAL X1 Large Jaw Tissue Sealer**Feb 14, 2017  
60 days to decisionK163548 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163548/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 16, 2016
Decision date	Feb 14, 2017
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163548/> 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 June 1, 2026