

K172580 ENSEAL X1 Tissue Sealer, Straight Jaw, 25 cm Shaft Length, ENSEAL X1 Tissue Sealer, Straight Jaw, 37 cm Shaft Length, 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 LengthNov 20, 2017
84 days to decisionK172580 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k172580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 28, 2017
Decision date	Nov 20, 2017
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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