

K180403 ENSEAL X1 Tissue Sealer, Curved Jaw, Articulating 37 cm Shaft LengthMay 23, 2018
98 days to decisionK180403 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 14, 2018
Decision date	May 23, 2018
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary
Other names	ENSEAL X1 Tissue Sealer, Curved Jaw, Articulating 45 cm Shaft Length

APPLICANT

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

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