

**K183435 Echelon Endoscopic Linear Cutter Reloads, White, Blue, Gold, Green and Black**Feb 6, 2019  
57 days to decisionK183435 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Dec 11, 2018
Decision date	Feb 6, 2019
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ethicon Endo-Surgery, LLC</b>
Location	Blue Ash, OH, US
Contact	Sigfrido Delgado
Website	<a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a>
510(k) history	70 submissions · 70 cleared · 2006-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ethicon Endo-Surgery, Inc.</b>
Contact	Brian Ruble

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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