

**K181620 Endoscopic Linear Cutting Staplers and Loading Units  
for Single Use**Sep 18, 2018  
90 days to decisionK181620 · Product code: **GDW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k181620/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jun 20, 2018
Decision date	Sep 18, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ezisurg (Suzhou) Medical Co., Ltd.</b>
Location	Suzhou, CN
Contact	Renjing Tian
510(k) history	2 submissions · 2 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181620/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026