

K211197 Disposable Endoscopic Cutter Stapler and CartridgeJan 19, 2023
638 days to decisionK211197 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Apr 21, 2021
Decision date	Jan 19, 2023
Days to decision	638 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Waston Medical Appliance Co., Ltd.
Location	Shanghai, CN
Contact	Ning Mao
510(k) history	5 submissions · 5 cleared · 2010-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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