

**K211811 Disposable Endoscopic Staplers and Reload Unit,
Disposable Hemorrhoidal Cutter Staplers, Disposable Linear
Cutter Staplers, Disposable Circular Staplers**Mar 3, 2022
265 days to decisionK211811 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jun 11, 2021
Decision date	Mar 3, 2022
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuxi Beien Surgery Device Co., Ltd.
Location	Wuxi, CN
Contact	Juan Li
510(k) history	1 submissions · 1 cleared · 2022-2022

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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211811/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026