

K211458 Disposable Anorectal Staplers, Disposable Intraluminal Staplers, Disposable Linear Cutting Staplers, Disposable Endoscopic Cutting StaplersDec 30, 2021
233 days to decisionK211458 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211458/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Staple, Implantable (GDW) |
| Date received | May 11, 2021 |
| Decision date | Dec 30, 2021 |
| Days to decision | 233 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ningbo Verykind Medical Device Co., Ltd. |
| Location | Ningbo, CN |
| Contact | Pengfei Hong |
| 510(k) history | 2 submissions · 2 cleared · 2021-2021 |

REGULATORY CONSULTANT

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|-----------------|-------------------------------------|
| 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)

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