CLEARED

K211811 Disposable Endoscopic Staplers and Reload Unit, Disposable Hemorrhoidal Cutter Staplers, Disposable Linear Cutter Staplers, Disposable Circular Staplers

Mar 3, 2022
265 days to decision

K211811 · 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