CLEARED

May 27, 2021
345 days to decision

K201639 Disposable Circular Staple, Disposable Hemorrhoidal Stapler, Disposable Linear Stapler and Reloads, Disposable Linear Cutter Stapler and Reloads, Disposable Endoscopic Linear Cutter Stapler and Reloads

K201639 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jun 16, 2020
Decision date	May 27, 2021
Days to decision	345 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Biosis Healing Biolog Ical Technology Co., Ltd.**
Location	Beijing, CN
Contact	Ting Jiang
510(k) history	7 submissions · 7 cleared · 2020-2024

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