FDA 510(k) Premarket Notification

K182217 Linear Cutter Staplers and Loading Units for Single Use, Circular Staplers for Single Use

CLEARED

Apr 16, 2019
244 days to decision

K182217 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Aug 15, 2018
Decision date	Apr 16, 2019
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ezisurg (Suzhou) Medical Co., Ltd.**
Location	Suzhou, CN
Contact	Jingtian Ren
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Ying Xu

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