FDA 510(k) Premarket Notification

K202291 Button Loop

CLEARED

Jan 8, 2021
149 days to decision

K202291 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k202291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 12, 2020
Decision date	Jan 8, 2021
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Yunyi (Beijing) Medical Device Co., Ltd.**
Location	Beijing, CN
Contact	Xiaowei Liu
510(k) history	2 submissions · 2 cleared · 2020-2021

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