FDA 510(k) Premarket Notification

K201139 WEGO-PDO Barbed Suture

CLEARED

Oct 20, 2020
175 days to decision

K201139 · Product code: **NEW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201139/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Apr 28, 2020
Decision date	Oct 20, 2020
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Foosin Medical Supplies Inc., Ltd.**
Location	Shanghai, CN
Contact	Zhipeng Yang
510(k) history	8 submissions · 8 cleared · 2014-2020

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