

**K201139 WEGO-PDO Barbed Suture**Oct 20, 2020  
175 days to decisionK201139 · Product code: **NEW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k201139/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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