

K183001 WEGO-PGLA RAPIDJan 28, 2019
90 days to decisionK183001 · Product code: **GAM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k183001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Oct 30, 2018
Decision date	Jan 28, 2019
Days to decision	90 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	Lei Tang
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183001/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026