

K183004 WEGO-PGA RAPIDJan 28, 2019
90 days to decisionK183004 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183004/>**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

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