

K173779 REXMONO, PDREXMar 12, 2018
90 days to decisionK173779 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Dec 12, 2017
Decision date	Mar 12, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sm Eng Co., Ltd.
Location	Sasang-Gu, KR
Contact	Soon-Gu Lee
510(k) history	5 submissions · 5 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	Wise Company, Inc.
Contact	Sanglok Lee

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

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