

K200392 REXSINJul 7, 2020
140 days to decisionK200392 · Product code: **GAM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k200392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Feb 18, 2020
Decision date	Jul 7, 2020
Days to decision	140 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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