

K173747 REXLENEDec 21, 2018
378 days to decisionK173747 · Product code: **GAW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	Dec 8, 2017
Decision date	Dec 21, 2018
Days to decision	378 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173747/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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