FDA 510(k) Premarket Notification

K173747 REXLENE

CLEARED

Dec 21, 2018
378 days to decision

K173747 · Product code: **GAW** · General & Plastic Surgery
Source: 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