

K161629 CRYLREXFeb 10, 2017
242 days to decisionK161629 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Jun 13, 2016
Decision date	Feb 10, 2017
Days to decision	242 days
Third-party review	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

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