

K212810 MONOFIX PGCL, knotless wound closure deviceAug 5, 2022
336 days to decisionK212810 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Sep 3, 2021
Decision date	Aug 5, 2022
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Samyang Holdings Corp., Ltd.
Location	Daedeok-Gu, KR
Contact	Ahram Kim
510(k) history	1 submissions · 1 cleared · 2022-2022

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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