

K180625 Rondek PGA Suture (Beige or Violet)May 10, 2018
62 days to decisionK180625 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Mar 9, 2018
Decision date	May 10, 2018
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rk Manufacturing Corporation
Location	Danbury, CT, US
Contact	Joshua Hubbard
510(k) history	1 submissions · 1 cleared · 2018-2018

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