

K080412 ABSORBABLE SYNTHETIC SUTURE WITH NEEDLE ATTACHMENT (PGA BRAIDED)Sep 4, 2008
202 days to decisionK080412 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k080412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Feb 15, 2008
Decision date	Sep 4, 2008
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Pudong Jinhuan Medical Products Co., Ltd.
Location	La Mirada, CA, US
Contact	BRANDON CHOI
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026