

K212603 Non Absorbable Surgical Nylon SutureDec 22, 2021
127 days to decisionK212603 · Product code: **GAR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyamide (GAR)
Date received	Aug 17, 2021
Decision date	Dec 22, 2021
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Haidike Medical Product Co., Ltd.
Location	Heze, CN
Contact	Lili Xu
510(k) history	2 submissions · 2 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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