

K220219 PERMALOOP Suture, PERMATAPE SutureApr 26, 2022
90 days to decisionK220219 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Jan 26, 2022
Decision date	Apr 26, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	Ashley Aromando (Goncalo)
510(k) history	96 submissions · 96 cleared · 2010-2026

REGULATORY CONSULTANT

Consulting firm	Depuy Synthes Mitek Sports Medicine
Contact	Ashley Aromando (Goncalo)

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220219/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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