

K233265 Monotime and Optime ROct 11, 2024
378 days to decisionK233265 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Sep 29, 2023
Decision date	Oct 11, 2024
Days to decision	378 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Peters Surgical
Location	Bobigny, FR
Contact	Ellen Henke Knupp
510(k) history	7 submissions · 7 cleared · 2005-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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