

K251648 GPS Advanced

Jun 24, 2025
26 days to decision

K251648 · Product code: **FMF** · Orthopedic
Source: <https://www.510kdatabase.net/k251648/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	May 29, 2025
Decision date	Jun 24, 2025
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GPS Advanced Cannula

APPLICANT

Company	Prosidyan, Inc.
Location	Philedelphia, PA, US
Contact	Tamala Wampler
510(k) history	12 submissions · 12 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	DePuy Synthes
Contact	Karin McDonough

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

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Device record: <https://www.510kdatabase.net/k251648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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