FDA 510(k) Premarket Notification

# K241426 GPS Advanced

**CLEARED**

Jul 10, 2024
51 days to decision

K241426 · Product code: **FMF** · Orthopedic
Source: https://www.510kdatabase.net/k241426/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | May 20, 2024 |
| Decision date | Jul 10, 2024 |
| Days to decision | 51 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | 5 cc 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