June 24, 2025

Prosidyan, Inc.
% Karin McDonough
Senior Regulatory Affairs Program Lead
DePuy Synthes
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K251648
Trade/Device Name: GPS Advanced and GPS Advanced Cannula
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: May 29, 2025
Received: May 29, 2025

Dear Karin McDonough:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2025.06.24 14:47:40 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251648

Device Name
GPS Advanced and GPS Advanced Cannula

Indications for Use *(Describe)*
GPS Advanced and GPS Advanced Cannula are intended for use to deliver FIBERGRAFT™ BG Putty GPS to a bone grafting site.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

A. Submitter Information

510(k) Sponsor:	Prosidyan, Inc. 41 Spring Street #107 New Providence, NJ 07974 USA
Submitter:	DePuy Synthes 325 Paramount Drive Raynham, MA 02767 USA
Contact Person:	Karin McDonough Senior Regulatory Affairs Program Lead DePuy Synthes kmcdono3@its.jnj.com

B. Date Prepared May 29, 2025

C. Device Name

Trade/Proprietary Name:	GPS Advanced and GPS Advanced Cannula
Common/Usual Name:	Syringe, Piston
Device Classification:	Class II
Regulation:	21 CFR §880.5860 – Piston Syringe
Classification Product and Panel Code:	FMF – General Hospital & Personal Use

D. Predicate Device Names

Primary Predicate Device:	GPS Advanced and GPS Advanced Cannula (K241426), FMF
Reference Device:	Allograft MIS Delivery System (K201338), FMF

E. Device Description

GPS Advanced is a sterile, single use dispenser for the delivery of FIBERGRAFT™ BG Putty GPS bone graft substitute. The dispenser has a ratcheted plunger that advances with each squeeze of its handle. The 5 cc GPS Advanced Cannula ("GPS Advanced Cannula") is available individually packaged and can be attached to the dispenser.

GPS Advanced is provided sterile via irradiation and GPS Advanced Cannula is provided sterile via ethylene oxide.

The GPS Advanced Cannula is provided empty and needs to be filled with FIBERGRAFT™ BG Putty GPS prior to use. FIBERGRAFT™ BG Putty GPS is a bioactive synthetic bone graft substitute in putty format made from 45S5 bioactive glass and has been previously cleared under K170306 (FIBERGRAFT™ BG Putty – Bone Graft Substitute) and K222276 (CONDUIT™ Cages and FIBERGRAFT™ BG Putty). FIBERGRAFT™ BG Putty GPS is not included in the GPS Advanced dispensing system.

F. Indications for Use

GPS Advanced and GPS Advanced Cannula are intended for use to deliver FIBERGRAFT™ BG Putty GPS to a bone grafting site.

G. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The technological characteristics, including design, materials, principle of operation and performance as well as intended use of GPS Advanced and GPS Advanced Cannula are consistent with those of the primary predicate and reference device.

H. Performance Data

The performance data for the subject devices consists of the following evaluations:

- Biological Risk Assessment
- Sterilization Validation
- Packaging and Shelf-Life Testing, including functional evaluation

I. Conclusion

The indications for use of the GPS Advanced and GPS Advanced Cannula are consistent with those of the predicate device. The technological characteristics of the GPS Advanced in terms of design, materials, principle of operation and performance are consistent with those of the predicate devices. GPS Advanced is substantially equivalent to the predicate device.