510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the *nSTRIDE® PRP Concentration System* 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s,' issued on September 13, 2019.

Sponsor	Biomet Biologics, Inc. 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581, USA Establishment Registration Number: 1825034
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Date Prepared	May 11, 2023
Subject Device	**Trade Name:** *nSTRIDE® PRP Concentration System* **Common Name:** Automated blood cell separator **Product Code:** ORG **Regulatory Class:** II **Classification Name:** • 21 CFR 864.9245 – Platelet and Plasma Separator for Bone Graft Handling

Predicate and Reference Device(s)

510(k) Number	Device Name	Manufacturer
BK070026 **(Predicate)**	GPS® III Platelet Concentrate Separation Kit with ACD-A	**Biomet Biologics, Inc.** 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581, USA
BK050016 **(Reference)**	Plasmax® Plus Plasma Concentrator with GPS® III Platelet Concentrate Separation Kit with ACD-A (Previously known as Fibrostik® Plasma Concentrator)	**Biomet Biologics, Inc.** 56 East Bell Drive P.O. Box 587 Warsaw, IN 46581, USA

Purpose and Device Description

The purpose of this submission is to obtain clearance for the subject device, *nSTRIDE® PRP Concentration System*.

The *nSTRIDE® PRP Concentration System* is intended to produce Platelet-Rich Plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP contains a concentration of platelets above baseline whole blood. This PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

The PRP is produced through processing anticoagulated whole blood through two sterile single-use and multi-compartmental devices:

GPS III Separator Device with ACD-A

The GPS III Separator device with ACD-A (Anticoagulant Citrate Dextrose Solution, Solution A, USP) aids separation of the patient's own blood components by density through the use of a Zimmer Biomet centrifuge.

nSTRIDE® PRP Concentrator

The nSTRIDE PRP Concentrator aids in the concentration of the patient's own plasma proteins by centrifugation utilizing a Zimmer Biomet centrifuge. Excess water is removed from the platelet-rich-plasma (PRP) with dehydrating beads to create PRP.

The devices are not made with natural rubber latex. The materials used for the GPS III Separator and nSTRIDE Concentrator consist of polymers and elastomers suitable for use in medical devices.

Output Characterization

The output (concentrated PRP) obtained by using the *nSTRIDE PRP Concentration System* retains the required characteristics of PRP in a reduced volume (at least 250,000 platelets per microliter and pH above 6.2).

Similarly, bone graft handling testing demonstrated the ability to clot via coagulation cascade remains unchanged when concentrating PRP with the *nSTRIDE® PRP Concentration System*.

Intended Use and Indications for Use

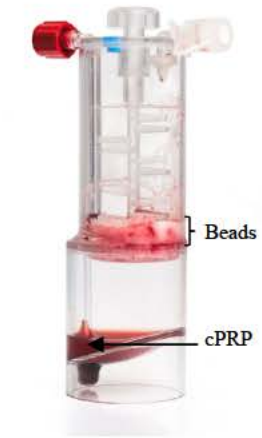
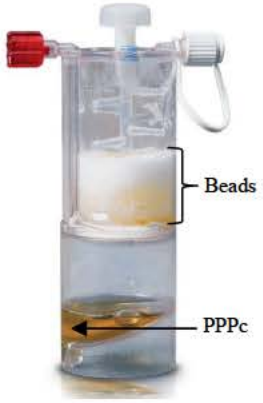
Intended Use	The *nSTRIDE® PRP Concentration System* is intended for point of care processing of autologous blood for bone graft handling applications.
Indications for Use	The *nSTRIDE® PRP Concentration System* with GPS® III Separator device with ACD-A is indicated for the safe and rapid preparation of autologous Platelet-Rich Plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics compared to the predicate and reference devices:

- **Intended Use:** Equivalent to predicate and reference devices.
- **Indications for Use:** Equivalent to predicate and reference devices.
- **Materials:** Identical to predicate and reference devices.
- **Design Features:** Equivalent to predicate and reference devices.
- **Sterilization method:** Identical to predicate and reference devices.
- **Packaging:** The subject device has equivalent packaging to predicate and reference devices.

Technological comparison

Property or Characteristic	**Subject Device** nSTRIDE® PRP Concentration System	**Predicate Device** GPS® III Platelet Concentrate Separation Kit with ACD-A **BK070026**	**Reference Device** Plasmax® Plus Plasma Concentrator with GPS®III Platelet Concentrate Separation Kit with ACD-A **BK050016**	**Equivalency**
Representative Device Image	GPS III Separator:  nSTRIDE PRP Concentrator: 	GPS III Separator: 	GPS III Separator:  Plasmax Plus Plasma Concentrator: 	GPS III Separator is the same in subject, predicate and reference devices. Concentrator devices are identical except for: - Mass of the beads - Concentrated output Differences between subject and reference devices do not raise any different questions of safety and effectiveness.
Product Code	ORG	ORG*	ORG*	Identical to predicate and reference devices *Assigned as per FDA suggestion
Regulation Number	21 CFR 864.9245	21 CFR 864.9245*	21 CFR 864.9245*	Identical to predicate and reference devices

				*Assigned as per FDA suggestion
Principle Operation	- Isolate targeted cell fractions by density utilizing centrifugation - Concentration via dehydrating beads	- Isolate targeted cell fractions by density utilizing centrifugation	- Isolate targeted cell fractions by density utilizing centrifugation - Concentration via dehydrating beads	Identical to Primary and Reference Devices
Blood Component separation method	Centrifugation	Centrifugation	Centrifugation	Identical to predicate and reference devices
Processing Fluid and Approximate Volumes	GPS III Separator: Anticoagulated Whole Blood: 60mL nSTRIDE PRP Concentrator: PRP: 6 mL	GPS III Separator: Anticoagulated Whole Blood: 60mL	GPS III Separator: Anticoagulated Whole Blood: 60mL Plasmax Plus Plasma Concentrator: Platelet Poor Plasma (PPP): 25 mL	Identical processing fluid and approximate volume for the GSP III Separator device in subject, predicate and reference devices Differences between subject and reference do not raise any different questions of safety and effectiveness
Materials	Polymeric Medical Grade Plastics	Polymeric Medical Grade Plastics	Polymeric Medical Grade Plastics	Identical to predicate and reference devices
Clotting Ability / Platelet Function	Processing autologous whole blood through the nSTRIDE PRP Concentration System does not hinder the blood clotting mechanism via the coagulation cascade.	Processing autologous whole blood through the GPS III Platelet Concentrate Separation Kit with ACD-A does not hinder the blood clotting mechanism via the coagulation cascade.	<u>Plasmax Plus Plasma:</u> Final Output: Platelet Poor Plasma Concentrate (PPPc) Clotting Ability / Platelet Function: Non-Applicable	Identical to predicate

Bone Graft Handling	Processing autologous whole blood through the *nSTRIDE PRP Concentration System* does not hinder the formation of cohesive logs when mixed with bone graft material	Processing autologous whole blood through the *GPS III Platelet Concentrate Separation Kit with ACD-A* does not hinder the formation of cohesive logs when mixed with bone graft material	<u>Plasmax Plus Plasma:</u> Final Output: PPPc Bone Graft Handling: Non-Applicable	Identical to predicate
Biocompatibility	Meets ISO 10993-1 requirements for	Meets ISO 10993-1 requirements for	Meets ISO 10993-1 requirements for	Identical to predicate and reference devices
Packaging	Packaged in industry – standard gamma compatible sterile barrier materials using industry-standard package sealing processes, and then into a retail paperboard carton.	Packaged in industry – standard gamma compatible sterile barrier materials using industry-standard package sealing processes, and then into a retail paperboard carton.	Packaged in industry – standard gamma compatible sterile barrier materials using industry-standard package sealing processes, and then into a retail paperboard carton.	Identical to predicate and reference devices
Anatomy	Orthopedic surgical site as deemed necessary by the clinical use requirements	Orthopedic surgical site as deemed necessary by the clinical use requirements	Orthopedic surgical site as deemed necessary by the clinical use requirements	Identical to predicate and reference devices
Sterilization	<u>Devices:</u> Sterile, Gamma irradiation	<u>Devices:</u> Sterile, Gamma irradiation	<u>Devices:</u> Sterile, Gamma irradiation	Identical to predicate and reference devices
Shelf Life	5 years – Devices 3 years – ACD-A Labeled shelf life does not exceed expiration date of earliest expiring component	5 years – Devices 3 years – ACD-A Labeled shelf life does not exceed expiration date of earliest expiring component	5 years – Devices 3 years – ACD-A Labeled shelf life does not exceed expiration date of earliest expiring component	Identical to predicate and reference devices
Anti-Coagulant	ACD-A	ACD-A	ACD-A	Identical to predicate and reference devices

Summary of Performance Data to Support Substantial Equivalence (Nonclinical and/or Clinical)

Non-Clinical Tests:
All necessary non-Clinical testing was conducted to support and establish substantial equivalence, in terms of safety and performance, between subject and identified predicate and reference devices:

- Platelet Clotting
- Bone Graft Handling
- Platelet Concentration
- Output pH
- Output Volume
- Biocompatibility Evaluation
- Sterilization Validation
- Packaging Testing

Clinical Tests:

- No clinical testing was performed. Clinical data and conclusions were deemed not necessary to establish substantial equivalence between the subject device, *nSTRIDE® PRP Concentration System,* and the identified predicate.

Animal Testing

- No animal testing was performed. Animal data and conclusions were deemed not necessary to establish substantial equivalence between the subject device, *nSTRIDE® PRP Concentration System*, and the identified predicate.

Substantial Equivalence Conclusion

The proposed *nSTRIDE® PRP Concentration System* has equivalent intended use and indications for use to the predicate device. The proposed device has equivalent technological characteristics to the predicate and reference devices, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate and reference devices.