510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Fidia PRP Kit 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

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Date Prepared: October 31, 2019

Proposed Class: II

Proprietary Name: Fidia PRP Kit

Common Name: Platelet and Plasma Separator for Bone Graft Handling

Classification Name: Automated Blood Cell Separator

Regulation Number: 21 CFR 864.9245

Product Codes: ORG

Predicate Device(s):

Manufacturer	Device Name	510(k) Number	Procode	Class
Alliance Partners, LLC (dba Alliance Spine)	Cyclone® Platelet Rich Plasma (PRP) Concentrating System	BK160045	ORG	II
Reference Device:				
B.T.I. Technology Institute	Endoret® Kit	BK150294 BK130049	ORG	II

Indications for Use

The Fidia PRP Kit is designed to be used 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.

Device Description

The Fidia PRP Kit is a sterile, single-use kit comprised of blood collection components, syringes, and the components necessary for processing the blood sample. The collected blood sample is transferred to the processing tube and placed into a general-purpose centrifuge. After centrifugation, the desired amount of PRP can be isolated in the syringe.

The materials of the Fidia PRP Kit include nickel-chromium steel for the extraction needles, plastics for the tubing, and silicone for the pistons and valves.

Technological Characteristics and Substantial Equivalence

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation are similar between the subject Fidia PRP Kit and the predicate device. Any differences between the subject and predicate device would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness. The following table outlines the comparison of the technological characteristics between the subject Fidia PRP Kit, the predicate Cyclone® Platelet Rich Plasma (PRP) Concentrating System, and the reference Endoret® Kit used for performance testing:

Characteristics	Fidia PRP Kit (Subject device)	Cyclone PRP Concentrating System (Predicate device)	Endoret® Kit (Reference device for equivalence testing)	Equivalence Assessment
510(k) number	Not assigned	BK160045	BK150294	N/A
Manufacturer	Fidia Farmaceutici S.p.A.	Alliance Partners, LLC	B.T.I Biotechnology Institute, SL.	N/A
Regulation	21 CFR 864.9245	21 CFR 864.9245	21 CFR 864.9245	Identical
Product Code	ORG	ORG	ORG	Identical
Indications for Use and Device description				
Indications for Use Statement	The Fidia PRP Kit is designed to be used 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.	The Cyclone® Platelet Rich Plasma (PRP) Concentrating System is designed to be used 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.	The ENDORET® KIT is designed to be used 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.	Identical
System Components	Disposable concentrating device (tube) packaged with syringes, blood draw needles and blood draw accessories	Disposable concentrating device (tube) packaged with syringes, blood draw needles and blood draw accessories	Disposable concentrating device (tube) packaged with syringes, blood draw needles and blood draw accessories	Identical
Materials	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Identical
Device Technology				
Principle of Operation	Separation of blood based	Separation of blood based	Separation of blood based	Identical

Characteristics	Fidia PRP Kit (Subject device)	Cyclone PRP Concentrating System (Predicate device)	Endoret® Kit (Reference device for equivalence testing)	Equivalence Assessment
	on density	on density	on density	
Process for PRP/PPP Collection	Entire plasma fraction collected/ No PPP fraction	PRP and PPP collected separately	Entire plasma fraction collected/ No PPP fraction	Identical to Endoret
Method of Processing	Centrifugation	Centrifugation	Centrifugation	Identical
Centrifuge Device	General purpose centrifuge	General purpose centrifuge	General purpose centrifuge	Identical
Sterile	Yes	Yes	Yes/ No	Identical to Cyclone, similar to Endoret

Performance Data

The following performance data were provided in support of the substantial equivalence decision:

Biocompatibility Testing:

Biocompatibility testing on the patient contacting materials of the device was conducted in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process". The Fidia PRP concentrating device is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity, sensitization & irritation, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility.

Bench Testing:

Performance testing was conducted with the BTI Endoret® Kit to determine the platelet concentration quality and mechanical testing of the tubes. Testing was performed in a paired design with the Endoret® Kit using an Eppendorf centrifuge, Model 5702. The centrifuge had the following specifications: Swinging rotors (with adaptors to fit buckets compatible with the centrifuge), Round bucket configuration of 40mm in diameter and 80mm in height, relative

centrifugal force of 435g at room temperature, and spun for 8 minutes.

The following bench testing was conducted in comparison with the reference device:

- pH;
- Blood cell count (RBC, WBC);
- Platelet count;
- Platelet recovery;
- Platelet concentration factor;
- P-selectin expression on platelets;
- Hypotonic stress response;
- Platelet aggregation (collagen); and
- Bone graft cohesion testing

The results obtained demonstrate substantial equivalence of the subject Fidia PRP Kit to the reference device for all parameters evaluated.
Structural integrity testing of the tubes was conducted after worst case conditioning. Results showed the tubes maintain structural integrity when subjected to worst case centrifugal conditions.

Conclusions:

Performance testing and comparison of characteristics between the subject, predicate, and reference device has demonstrated that the Fidia PRP Kit is substantially equivalent to the predicate device with regard to materials, intended use, operation, function, and technological characteristics.

Iris Marklein -S

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