510(k) SUMMARY – BK251157

1. SUBMITTER INFORMATION

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2. DEVICE NAME AND CLASSIFICATION

Name of device:	ENDORET® Kit
Regulation Number:	21 CFR 864.9245
Regulation Description:	Automated blood cell separator
Regulatory Class:	Class II
Product Code:	ORG
Classification Panel:	Hematology

3. PREDICATE AND REFERENCE DEVICES

Primary predicate device:

- BK150294 ENDORET® Kit, B.T.I. Biotechnology Institute, S.L.

Reference device:

- BK130049 ENDORET® Kit, B.T.I. Biotechnology Institute, S.L.

4. INDICATIONS FOR USE

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.

5. DEVICE DESCRIPTION

The ENDORET® Kit includes sterile, single use components to draw blood by vacuum from at a patient's point-of-care and separate the blood components by centrifugation to create a platelet-rich plasma (PRP) output, that is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. The ENDORET® Kit is intended to be used under the supervision of a healthcare professional.

The ENDORET® kit includes blood collection tubes with anticoagulant, blood collection needles, Plasma Transfer Device to collect the PRP fraction in sterile fractionation tubes, and an activator agent that is added to the PRP prior to its application. This ENDORET® Kit includes modified or additional components.

The materials of the ENDORET® Kit components are medical grade polymers, elastomers, rubbers and stainless steel suitable for use in medical devices. These components are provided sterile by irradiation, ethylene oxide or autoclave.

Additional equipment used for blood centrifugation is available and sold separately to the end-user in order to operate the device as intended.

6. PERFORMANCE DATA

Non-clinical testing information submitted in order to demonstrate substantial equivalence of the proposed device include:

- Sterilization validation for subject device components, provided sterile, to a sterility assurance level (SAL) of 10^{-6}, according to ISO 11137-1, ISO 11137-2 and ISO 17665-1.
- Biocompatibility testing for new or modified device components, according to ISO 10993-4, ISO 10993-5, ISO 10993-10, and ISO10993-11.
- Sterile Barrier/Shelf-Life validation according to ISO 11607-1, ASTM F88, ASTM F1886/F1886M, ASTM 1929, ASTM F1140/F1140M and ASTM F2096.
- Comparative performance bench testing, including measurements of the following parameters:
    - Platelet concentration factor
    - Platelet yield
    - pH
    - platelet aggregation
    - platelet activation
    - clot integrity of the composite clot formed with bone graft material and PRP.

  The results obtained in the study demonstrate substantial equivalence performance between the PRP obtained with subject and predicate ENDORET® kit.

No clinical data were included in this submission.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE DISCUSSION

The proposed device is substantially equivalent in Indications for Use, operating principle and design to the primary predicate and reference devices identified above. Table 1 below compares the subject device to the predicate and reference devices indications for use and technological characteristics.

The subject ENDORET® Kit is substantially equivalent to the ENDORET® kit currently cleared in BK150294 in design, materials, manufacturing processes, sterilization and shelf-life. Reference device ENDORET® kit, cleared in BK130294 is in support of fractionation tube included in selected subject device models.

8. CONCLUSION

The subject device components have identical Indications for use and equivalent technological characteristics of primary predicate and reference device identified above. The subject device has identical intended use and shares basic design features with the already cleared ENDORET® Kits. The subject device, predicate device and reference device include components to obtain a Platelet-rich Plasma output by centrifugation. The subject device includes modified or additional components that do not raise new concerns of safety and effectiveness.

The information included in this submission demonstrates that the subject ENDORET® Kit is substantially equivalent to the identified predicate and reference devices.

Table 1. Substantial Equivalence – Indications for use and technological characteristics comparison

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	ASSESSMENT
Name	**ENDORET® Kit**	**ENDORET® Kit (BK150294)**	**ENDORET® Kit (BK130049)**	(not applicable)
Product Classification	Product Code: ORG Regulation No.: 21 CFR 864.9245 Device Class II	Product Code: ORG Regulation No.: 21 CFR 864.9245 Device Class II	Product Code: ORG Regulation No.: 21 CFR 864.9245 Device Class II	Identical.
Indications for Use (STATEMENT)	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.	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.	The 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.	Identical to BK150294. Very similar wording is included in BK130049, for same intended use.
Principle of operation	Separation of blood fractions by density.	Separation of blood fractions by density.	Separation of blood fractions by density.	Identical.
Blood Component separation method	Centrifugation	Centrifugation	Centrifugation	Identical.
Device components	Blood collection tubes, anticoagulated.	Blood collection tubes, anticoagulated.	Blood collection tubes, anticoagulated.	Equivalent. Very similar or identical components included in predicate and reference device are included in subject device. Identical anticoagulant and activator agents are used in subject, predicate and reference devices. The additional components inclusion does not modify the intended use of the device.
	Blood collection set.	Blood collection set.	Blood collection set.	
	Plasma Transfer Device.	Plasma Transfer Device.	Plasma Transfer Device.	
	Fractionation tubes (evacuated and non-evacuated).	Fractionation tubes (non-evacuated).	Fractionation tubes (evacuated).	
	ENDORET Activator.	ENDORET Activator.	ENDORET Activator.	
	Syringe for Activator.	Syringe for Activator.	Syringe for Activator.	
	Additional caps, connectors and needles.	-	-	
Sterilization	Device components provided sterile.	Device components provided sterile.	Device components provided sterile.	Identical
Shelf-life	18 months	12 months	12 months	Equivalent. Shelf-life analyses performed and provided in this submission support this extended shelf life for subject device.