510(k) Summary

5.1 Submitter

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5.2 Device

Name of Device:	Cyclone® Concentrating System
Common Name:	Platelet and Plasma Separator for Bone Graft Handling
Classification Name:	Automated Blood Cell Separator (21 CFR 864.9245)
Regulatory Class:	Class II
Product Code:	ORG

5.3 Predicate Device

Alliance Partners Cyclone PRP Concentrating System [BK160045]

5.4 Reason for 510(k) Submission:

The purpose of this submission is to gain clearance for a device that is intended to be a line extension of the Cyclone Platelet Rich Plasma (PRP) Concentrating System cleared under BK160045. This line extension expands the indications for use to include a mixture of peripheral blood and bone marrow as the starting source material (input) to the intended use of the device, which is to prepare and produce platelet concentrate (platelet rich plasma or PRP). The expansion of the indications for use does not alter the fundamental scientific technology of the device, nor the materials of construction, processing methods and mechanism of operation.

5.5 Device Description

The Cyclone Concentrating System is a single-use, sterile kit consisting of a bone marrow aspiration (BMA) needle, syringes, a filter assembly, and concentrating device(s). It concentrates a mixture of peripheral blood and bone marrow and aids in separation of the mixture of peripheral blood and bone marrow by density through the use of its components, specifically the concentrating device, and a standard, general purpose centrifuge.

The system permits platelet concentrate (platelet rich plasma or PRP) to be rapidly prepared from a small volume of a mixture of peripheral blood and bone marrow that is drawn at the time of treatment. Platelet Rich Plasma prepared from a mixture of peripheral blood and bone marrow may contain higher levels of plasma free hemoglobin than Platelet Rich Plasma prepared from peripheral blood.

The materials of the system's components consist of medical grade polymers, elastomers and stainless steels suitable for use in medical devices.

5.6 Indications for Use

The Cyclone Concentrating System is designed to be used intraoperatively at the point of care for the safe and rapid preparation of a platelet concentrate (platelet rich plasma or PRP) from a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improved handling characteristics.

5.7 Comparison of Technological Characteristics with Predicate Device

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation are similar between the subject Cyclone Concentrating System and the predicate Cyclone PRP Concentrating System. Both are provided as sterile concentrating systems, designed to concentrate and aid in separation of a starting source material (a mixture of peripheral blood and bone marrow or peripheral blood only) by density through the use of a centrifuge. Both are made of medical grade polymers, elastomers and stainless steels suitable for use in medical devices. Both include a single-use, disposable receptacle (e.g. concentrating device, separator, centrifuge tube assembly, etc.) that is designed to accept a volume of a mixture of peripheral blood and bone marrow or peripheral blood only, and then undergo centrifugal processing, in order to obtain platelet concentrate (PRP). Slight differences between the subject and predicate devices include the addition of a mixture of peripheral blood and bone marrow as a device input and addition of a filter assembly to remove particulate that may be in the aspirated bone marrow prior to centrifugal processing. As verified by platelet concentrate quality testing and filter assembly testing, the subject Cyclone Concentrating System performs as it is intended to for all parameters evaluated, therefore, demonstrating the differences do not affect a determination of substantial equivalence. Table 5-1 summarizes the comparison of technological characteristics between the subject and predicate devices.

Table 5-1: Technological Characteristics Comparison

	Subject Device	**Predicate Device**
	Cyclone Concentrating System	**Cyclone PRP Concentrating System**
Indications for Use	The Cyclone Concentrating System is designed to be used intraoperatively at the point of care for the safe and rapid preparation of a platelet concentrate (platelet rich plasma or PRP) from a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improved 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.

	Subject Device	Predicate Device
	Cyclone Concentrating System	**Cyclone PRP Concentrating System**
Intended Use	To prepare and produce platelet concentrate (platelet rich plasma or PRP)	To prepare and produce platelet concentrate (platelet rich plasma or PRP)
System Components	Disposable concentrating device (receptacle) packaged with syringes, BMA needle and filter	Disposable concentrating device (receptacle) packaged with syringes, blood draw needles and blood draw accessories
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
Principle of Operation	Separation of a mixture of peripheral blood and bone marrow based on density	Separation of peripheral blood based on density
Method of Processing	Centrifugation	Centrifugation
Centrifuge Device	General purpose centrifuge	General purpose centrifuge
Sterile	Yes	Yes

5.8 Performance Data / Non-clinical Tests

The following performance data were provided in support of the substantial equivalence determination.

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. Per ISO 10993-1, the Cyclone concentrating device is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity (per ISO 10993-5), sensitization & intracutaneous reactivity (per ISO 10993-10), acute systemic toxicity (per ISO 10993-11), and pyrogenicity (per ANSI/AAMI ST72, USP<151>, ISO 10993-11).

Bench Testing:

A study evaluating platelet concentrate quality was conducted with the Cyclone Concentrating System using a mixture of peripheral blood and bone marrow collected from healthy human donors for processing into platelet rich plasma. The following platelet concentrate quality tests were performed: blood cell counts (platelets, erythrocyte cells, and leukocyte/total nucleated cells), platelet concentration factor, platelet yield, pH, platelet activation (resting and ADP stimulated), platelet aggregation, hypotonic stress response, and clot integrity. The results obtained demonstrate substantial equivalence of the Cyclone Concentrating System to the predicate device.

Testing was conducted to evaluate the packaging system for the Cyclone Concentrating System. Testing involved subjecting devices to simulated distribution, followed by visual inspection, and evaluation of seal strength and

packaging integrity. The results obtained demonstrate that the packaging system adequately protects the device during shipping and transportation. The device is in compliance with the acceptance criteria established for all parameters evaluated.

Testing was conducted to evaluate the functional and structural integrity of the Cyclone concentrating device. Testing involved subjecting devices to simulated intended in-use conditions. The results obtained demonstrate that the device's structural and functional integrity remain intact after its recommended use. The device is in compliance with the acceptance criteria established for all parameters evaluated.

Testing was conducted to evaluate the functional and structural integrity of the Cyclone filter assembly. Testing included flow rate, tensile strength, burst pressure, and liquid leakage. The results obtained demonstrate the device performs as its intended to. The device is in compliance with the acceptance criteria established for all parameters evaluated.

5.9 Conclusions:

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