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510(k) Summary

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I. Submitter

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II. Device

Trade Name:	Bone Marrow Collection Stand Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters*
Common or Usual Name:	Bone Marrow Collection Kit and Accessories
Product Code:	LWE
Classification Name:	Unclassified – Pre-Amendment
Review Panel:	80 LWE (General Hospital) Bone Marrow Collection/Transfusion Kit
Device Class:	Unclassified (Pre-Amendment)
Model Numbers/Article Codes:	(4R2105, X6R2105) Bone Marrow Collection Stand (X6R2107, R6R2107) Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters ***The subject of this 510(k)**

III. Primary Predicate Device

Trade Name:	Bone Marrow Collection Stand Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters
Common or Usual Name:	Bone Marrow Collection Kit and Accessories
510(k) Number:	BK160042
Product Code:	LWE (General Hospital) Bone Marrow Collection/Transfusion Kit
Device Class:	Unclassified (Pre-Amendment)

IV. Device Description

This product is a system consisting of a flexible plastic collection bag, a series of flexible inline filters for the removal of material greater than or equal to 200 microns, flexible plastic containers for the receipt of the filtered product, sterile wraps for use as a sterile field, and a stainless steel sterilized stand for the support of the collection bag during collection.

The Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters is used for the collection and filtration of aspirated bone marrow in preparation for bone marrow transplantation. When in use the collection container is placed in the sterilized stand near the intended site of marrow procurement and the outlet clamp is closed. At the completion of marrow harvest or when the container is full, the snap-lock lid on the collection container is closed and the container is removed from the stand and transferred to the area where the filtration procedure is to be performed.

The Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters is a sterile, disposable system. The collection and post-filtration containers are manufactured from plastic sheeting, a material widely used for blood component collection, preparation and storage. The marrow collection container, which is attached to the support stand, holds approximately 1.2L. Filtered marrow is received in one, two or three 600 mL Polyvinyl Chloride (PVC) plastic transfer pack units or in a 2-liter PVC plastic container transfer pack unit. The system is designed to permit easy filter replacement should filter plugging occur. Each bone marrow kit is supplied with two 500 micron filters and one 200 micron filter. Each kit is designed for single use and is disposable.

The configuration of the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters consists of:

1 – 1.2 Liter Collection Container with 850 micron Pre-filter
2 – 500 micron Plastic Mesh Filters in flexible plastic housing (red)

1 – 200 micron Plastic Mesh Filters in flexible plastic housing (blue)
3 – 600 mL Transfer Pack Containers
1 – 2000 mL Transfer Pack Container
1 – Plastic Pouch containing four non-vented tip protectors
2 – Sterile Wraps

The non-sterile Bone Marrow Collection Stand made of stainless steel is used to hold and stabilize the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters. The stand consists of a base, support rod (pole), collection container support with thumbscrew, and a collection container retainer. The support stand, which may be reused, is sterilized prior to each use by means of moist heat/steam sterilization.

V. Modification to the Existing Device:

Modifications described in this Traditional 510(k) do not add, delete, or modify the description of the Bone Marrow Kit with Flexible Pre-Filter and Inline Filters and the Bone Marrow Collection Stand.

The currently marketed Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters has been modified to replace the Injection Y-Site assembly with a luer activated Needleless Injection Y-Site. The current Injection Y-Site is accessed by needles and the replacement component is accessed with a male luer and is therefore a Needleless Injection Y-Site. The Injection Y-Site no longer contains (b) (4) or Dry Natural Rubber. The labeling was updated to remove the statement "This Product Contains Dry Natural Rubber." The dimension of the Transfer Pack tubing and the roller clamp was changed to accommodate the change to the luer activated Needleless Injection Y-Site. The described changes do not change the fundamental scientific technology or principle of operation. Reference Section VIII.

VI. Indications for Use

The Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters and Bone Marrow Collection Stand are used for the collection and filtration of aspirated bone marrow in preparation for bone marrow transplantation.

NOTE - The change described in this Traditional 510(k) for the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters and Bone Marrow Collection Stand does not add, delete, or modify the indications for use of the device. The Ancillary Collection Container which is an accessory to the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters is discontinued and no longer available for sale, therefore it was removed from the indications for use statement. Obsoleting the ancillary collection container has no impact on the safety and effectiveness of the Bone Marrow Collection Kit when used according to the instructions for use.

VII. Legally Marketed Device under Substantial Equivalence is Being Cleared:

Fresenius Kabi is claiming substantial equivalence with the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters most recently cleared for market under BK160042. The Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters will have the same intended use as the originally cleared kit (K871198).

VIII. Comparison of Technological Characteristics with the Predicate Device

Technological characteristics of the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters remain the same as the currently marketed device. Modifications to replace the Injection Y-Site associated with this Traditional 510(k) does not add, delete, or modify the technological characteristic of the device. At a high level, a comparison table between the predicate device and the modified device is provided in the table below.

	Predicate Device	**Subject Device - Modified**
Device	**(X6R2107, R6R2107) Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters**	SAME
Intended Use	The Bone Marrow Collection Kit is intended for collection and filtration of aspirated bone marrow.	SAME
Configuration	1 – 1.2 Liter Collection Container with 850 micron Pre-filter 2 – 500 micron Plastic Mesh Filters in flexible plastic housing (red) 1 – 200 micron Plastic Mesh Filters in flexible plastic housing (blue) 3 – 600 mL Transfer Pack Containers 1 – 2000 mL Transfer Pack Container 1 – Plastic Pouch containing four non-vented tip protectors 2 – Sterile Wraps	SAME
Principle of Operation	Collection and filtration of aspirated bone marrow in preparation for bone marrow transplantation	SAME
Kit Sterilization	Ethylene Oxide	SAME
Sterility Claim	Sterile, non-pyrogenic	SAME
Sterility Assurance Level	10^{-6}	SAME
Shelf Life	36 months	36 months

	Predicate Device	Subject Device - Modified
Technological Differences:		
	Y-site: • Needle Injection Y-Site • Material for components of the Y-Site: (b) (4) • Y-site contains Dry Natural Rubber	Y-site: • Needleless Injection Y-Site • Material for components of the Y-Site: (b) (4) • Y-site does not contain Dry Natural Rubber
	Transfer Pack Tubing[2] • Material: PVC	Transfer Pack Tubing[1] • Material: PVC
	Transfer Pack Roller Clamp[2] • Material: Polymer	Transfer Pack Roller Clamp[2] • Material: Polymer

[1]The dimensions of the tubing and roller clamp were changed to accommodate the change in the Y-Site.

IX. Performance Data

Performance testing and data provided in previously cleared filings remains valid for demonstrating performance of the Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters and the Bone Marrow Collection Stand. The proposed change to the device is centered solely on the material changes of the luer activated Needleless Injection Y-site, the Transfer Pack PVC tubing and roller clamp. Additional testing conducted to support the proposed change included:

A. Functional Testing (includes shelf-life testing)

- Pull testing and pressure testing to evaluate bond integrity and sterility
- Roller clamp testing to evaluate proper closure

The results obtained demonstrate that the device functional integrity is maintained with the material changes of the Y-site, Transfer Pack tubing and roller clamp. The device is in compliance with the acceptance criteria established for all parameters evaluated.

B. Biocompatibility

The Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters does not contain direct patient-contacting components. There are components of the kit that come in contact with the bone marrow and the materials remain the same with the exception of the components of the

Luer activated Needleless Injection Y-Site, the Transfer Pack Assembly PVC tubing and roller clamp. With the exception of these components, all biocompatibility information for the Bone Marrow Collection Kit remains the same as previously submitted.

Biocompatibility test for the new materials (fluid and non-fluid contacting) were performed 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 Bone Marrow Collection Kit 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 and intracutaneous reactivity (per ISO 10993-10), acute system toxicity per (ISO 10993-11), coagulation, platelets and hemolysis (per ISO 10993-4), pyrogenicity (per ISO 10993-11) and USP <661>. All testing satisfied the established acceptance criteria and supports the use of the Bone Marrow Collection Kit with the luer activated Needleless Injection Y-Site.

X. Conclusions

The modification to the Bone Marrow Collection Kit does not change the fundamental scientific technology or principle of operation. Therefore, it is concluded that the Bone Marrow Collection kit with the luer activated Needleless Injection Y-Site described in this Traditional 510(k) is substantially equivalent to the predicate device.