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## 510(k) Summary

### Date Prepared:

May 6, 2016

### Owner/Operator

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## Device

Trade Name:	Bone Marrow Collection Stand* Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters Ancillary Bone Marrow Collection Container with Flexible Pre-Filter
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 (4R2108H) Ancillary Bone Marrow Collection Container with

## Flexible Pre-Filter

### **\*The subject of this 510(k)**

#### **Predicate Device**

Trade Name:	Bone Marrow Collection Stand* Bone Marrow Collection Kit with Flexible Pre-Filter and Inline Filters Ancillary Bone Marrow Collection Container with Flexible Pre-Filter
Common or Usual Name:	Bone Marrow Collection Kit and Accessories
510(k) Number:	BK090031
Date Cleared:	July 23, 2009
Product Code:	LWE (General Hospital) Bone Marrow Collection/Transfusion Kit
Device Class:	Unclassified (Pre-Amendment)

#### **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.

The Bone Marrow Collection Kit and Accessories are 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.

#### **Modification to the Existing Device:**

Modifications described in this Special 510(k) do not add, delete, or modify the description of the Bone Marrow Kit and Accessories. The labeling change is to modify the directions for use for the Bone Marrow Collection Stand to include validated Cleaning and Sterilization Instructions, and Reuse Life Instructions. The directions for use for the Bone Marrow Kit are being revised to align with the Bone Marrow Collection Stand directions for use. These changes are made for

compliance with the Guidance “Reprocessing Medical Devices in Health Care Settings: Validations Methods and Labelling – March 17, 2015.

### **Statement of Intended Use**

The Bone Marrow Collection Kit and Accessories are used for the collection and filtration of aspirated bone marrow in preparation for bone marrow transplantation.

### **Indications for Use**

The Bone Marrow Collection Kit, Ancillary Container, 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 Special 510(k) for the Bone Marrow Collection Kit and Accessories does not add, delete, or modify the indications for use of the device.

### **Comparison of Technological Characteristics with the Predicate Device**

Technological characteristics of the Bone Marrow Collection Kit and Accessories remain the same as the currently marketed device. Revising the labeling to modify the directions for use to add validated cleaning and sterilization instructions for the Bone Marrow Collection Stand associated with this Special 510(k) does not add, delete, or modify the technological characteristic of the device or the disposable kits.

### **Design Control Activities**

The labeling change described in this Special 510(k) has no impact on the design of the Bone Marrow Collection Kit and Accessories. This change is to only address the cleaning, sterilization and reuse life instructions for the Bone Marrow Collection Stand.

### **Performance Data**

Performance testing and data in previously cleared filings remains valid for demonstrating Bone Marrow Collection Kit and Accessories performance. Testing was conducted to establish validated cleaning and sterilization instructions for the Bone Marrow Collection Stand.

### **Conclusions**

The Bone Marrow Collection Kit and Accessories with updated labeling described in this Special 510(k) are substantially equivalent to the currently marketed product.