

## 510(k) Summary

**Device Trade Name:** Hemanext ONE

**Common Name:** Container for the processing and storage of Red Blood Cell components under reduced oxygen conditions

**Manufacturer:** Hemanext Inc.  
99 Hayden Ave., Suite 620  
Lexington, MA. 02421

**Contact:** Ms. Laura Daniels  
99 Hayden Ave.  
Building B, Suite 620  
Lexington, MA 02421  
781-301-7474  
[Laura.Daniels@Hemanext.com](mailto:Laura.Daniels@Hemanext.com)

**Prepared by:** (b) (4) [REDACTED]

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**Classification:** 21 CFR §864.9115  
Container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions

**Class:** II

**Product Codes:** QYC

**Indications for Use:** Blood container set used to process and store CP2D/AS-3 or ACD-A/AS-3 Red Blood Cells Leukocytes Reduced, O<sub>2</sub>/CO<sub>2</sub> Reduced. The Hemanext ONE system limits O<sub>2</sub> and CO<sub>2</sub> levels in the storage environment.

Hemanext ONE is intended to process the following:

- Whole Blood or Apheresis Derived CP2D/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC), that have been filtered within 8-hours of collection. Processing of Red Blood Cells with the Hemanext ONE system must be completed within 12 hours of collection.
- Apheresis Derived ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced

(LR RBC), that have been filtered within 8-hours of collection. Processing of Red Blood Cells with the Hemanext ONE system must be completed within 12 hours of collection.

- Whole Blood or Apheresis Derived CP2D/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC), that have been filtered within 30 hours of collection at 1-6°C. Processing of Red Blood Cells with the Hemanext ONE system must be completed within 72 hours of collection.
- Apheresis Derived ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC), that have been filtered within 30 hours of collection at 1-6°C. Processing of Red Blood Cells with the Hemanext ONE system must be completed within 72 hours of collection.
- Apheresis Derived ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC), that have undergone in-line filtration and have been stored at 1-6°C for up to 67 hours. Processing of Red Blood Cells with the Hemanext ONE system must be completed within 72 hours of collection.

The Red Blood Cells must be processed with the Hemanext ONE system at room temperature (20-26°C). Red Blood Cells Leukocytes Reduced, O<sub>2</sub>/CO<sub>2</sub> Reduced may be stored for up to 42 days at 1-6°C. The Hemanext ONE system is used for volumes no greater than 350 mL of LR RBC.

Refer to Table 1 for a summary of the processing specifications.

**Table 1: LR RBC and Processing Specifications Summary**

Collection Method	Anticoagulant / Additive Solution	Filtration	Hold Time	Hemanext ONE Agitation Time at 20-26°C	Hemanext ONE Completion Time
WB or Apheresis	CP2D/AS-3	Within 8 hours of collection at 20-26°C	Not Applicable	3 hrs ± 15 mins	Within 12 hours of collection
Apheresis	ACDA/AS-3*				
WB or Apheresis	CP2D/AS-3	Within 30 hours of collection at 1-6°C	Up to 67 hours of collection at 1-6°C	3.5 hrs ± 15 mins	Within 72 hours of collection
Apheresis	ACDA/ AS-3*				

\*Includes in-line filtration

**Device Description**

The Hemanext ONE system is a storage device that reduces oxygen and carbon dioxide levels from leukocyte reduced packed red blood cells. The Hemanext system is an assembly of two disposables: the Oxygen Reduction Bag (ORB) and the Hemanext Storage Bag (HSB).

### Description of Hemanext Process:

An LR RBC unit bag is connected using a sterile docking device to the ORB. The sorbent quilt between the inner bag and the barrier bag creates an O<sub>2</sub>/CO<sub>2</sub> depleted environment. LR RBCs are then transferred by gravity to the ORB inner bag.

Once the full unit volume is in the ORB inner bag; the Hemanext ONE system is transferred to a tray on an agitator at room temperature (20-26°C). Its contents are evenly distributed, creating a large thin layer of LR RBC contacting the inner surface of the ORB inner bag. The agitator moves in a side-to-side motion causing the LR RBC to travel within the inner bag in a wave-like motion at the same rate as the shaker, maintaining a constant agitation of RBC and additive solution.

The red blood cells in direct contact with the inner bag surface release oxygen through the material and into the O<sub>2</sub>/CO<sub>2</sub>-starved environment between the inner bag and barrier bag of the ORB.

At the end of agitation, the resulting deoxygenated LR RBC is transferred to the HSB in the kit. The HSB utilizes the same principles as the ORB to preserve a low oxygen and CO<sub>2</sub> environment within its contents. It utilizes a sorbent to maintain this environment and preserve the blood at low O<sub>2</sub> and CO<sub>2</sub> levels for its storage duration of up to 42 days. The HSB is also a transfusion ready device.

**Predicate Device:**

Hemanext ONE authorized via BR220665 serves as the primary predicate device.

**Technological Characteristics Comparison:**

The Hemanext ONE, which is the subject of this application, is essentially identical with respect to construction.

**Performance Testing – *In Vitro***

To support the proposed changes to the indication for use statement *in vitro* blood studies were completed to demonstrate that the Red Blood Cells met the following acceptance criteria.

- A one-sided 95% lower confidence limit for the true proportion of RBC units with hemolysis at day 42 of refrigerated storage of  $\leq 1\%$  is  $> 95\%$ .
- Post processing SO<sub>2</sub> must be  $< 20\%$  at 80% confidence and 80% reliability, and  $< 30\%$  for 100% of units.

**Nonclinical Testing:**

Verification/Validation activities and performance testing have been conducted to confirm the subject device meets the performance requirements under the indications for use conditions and to support substantial equivalence to the predicate devices, including the following:

- Sterilization, Endotoxin, Shelf-life Validation and container closure integrity evaluation
- Biocompatibility Evaluation included leached materials extracted under conditions similar to clinical use and a toxicologic risk assessment of those extracted or leached materials
- Mechanical testing, including Blood Study for the evaluation of oxygen and, if applicable, carbon dioxide levels during Red Blood Cell components storage.

**Conclusion:**

Hemanext ONE, which is the subject of this submission, is substantially equivalent to Hemanext ONE, authorized via BR220665.