

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K032827

B. Analyte:

N/A

C. Type of Test:

Kendall LIFETRACE Umbilical Blood Collection Kit

D. Applicant:

Tyco Healthcare

E. Proprietary and Established Names:

Kendall LIFETRACE Umbilical Blood Collection Kit

F. Regulatory Information:

1. Regulation section:
21 CFR 864.9100 Empty container for the collection and processing of blood and blood components
2. Classification:
Class II
3. Product Code:
KSR
4. Panel:
Hematology, 81

G. Intended Use:

1. Indication(s) for use:
The device is used for umbilical cord blood sampling and transfer. The device is intended for single use only.
2. Special condition for use statement(s):
N/A
3. Special instrument Requirements:
N/A

H. Device Description:

The Kendall LifeTrace Umbilical Blood Collection Device consists of a cup shaped body, divided in half. The top half is used to collect umbilical cord blood for analysis and has a lid. The bottom half contains an Angel Wing Transfer device that is used to

puncture the rubber stoppers of vacuum tubes. The device is used to facilitate the transfer of the collected blood from the top chamber to the tube.

I. Substantial Equivalence Information:

1. Predicate device name(s):
DeRoyal Surgical Umbilicup
2. Predicate K number(s):
K020753
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The device is intended for single use only. The device is used for cord blood sampling and transfer	Same
Materials	Polymer based	Same
Device Description	Cup shaped device to contain blood	Same
	Contains a rubber valve over the blood collection needle	Same
	Contains cap for upper chamber	Same
	Contains sterile evacuated EDTA and no-additive blood collection tubes	Same
Differences		
Item	Device	Predicate
Sterilization method	Irradiation	Ethylene oxide

J. Standard/Guidance Document Referenced (if applicable):

ISO 10993 for Biological Evaluation of Medical Devices Part-1

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

- a. *Precision/Reproducibility:*
N/A
- b. *Linearity/assay reportable range:*
N/A
- c. *Traceability (controls, calibrators, or method):*
N/A
- d. *Detection limit:*
N/A
- e. *Analytical specificity:*
N/A
- f. *Assay cut-off:*
N/A

2. Comparison studies:

- a. *Method comparison with predicate device:*
N/A
- b. *Matrix comparison:*
N/A

3. Clinical studies:

- a. *Clinical sensitivity:*
N/A
- b. *Clinical specificity:*
N/A
- c. *Other clinical supportive data (when a and b are not applicable):*
Biocompatibility Testing (Pass/Fail)

- 1. Biological Reactivity test, In-Vitro (Pass)
- 2. Limulus Amebocyte Lysate Procedure for Pyrogen Testing (Pass)
- 3. Biological Reactivity Test, In-Vivo (Pass)
- 4. Hemolysis Test (Pass)

Functional Testing

- 1. UBC device liquid holding capacity. (acceptance criteria met)
- 2. Integrity of the seal between the cap and funnel. (acceptance criteria met)
- 3. Integrity of the seal between the transfer set and the funnel. (acceptance criteria met)
- 4. Integrity of the seal between the rubber valve on the needle and the transfer set. (acceptance criteria met)
- 5. Integrity of the rubber valve after being punctured 8 times by a blood collection tube. (acceptance criteria met)
- 6. Ability to aspirate liquid into the evacuated blood collection tube while the cap is attached. (acceptance criteria met)

4. Clinical cut-off:

N/A

5. Expected values/Reference range:
N/A

M. Conclusion:

The Kendall LifeTrace Umbilical Blood Collection Kit has been shown to be substantially equivalent to the DeRoyal Surgical Umbilicup.