



510(k) Summary

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Device Information

TRADE Name: Ortho® Elution Kit
Common Name: Blood bank supplies
Classification Name: Supplies, Blood-Bank
Regulation Number: 21 CFR 864.9050
Review Panel: Hematology
Product Code: KSS
Device Class: 1

Legally Marketed Predicate Device

| Predicate # | Predicate Trade Name | Product Code |
|-------------|----------------------|--------------|
| BK830014 | Elu-Kit II | KSS |

Device Description Summary

The Ortho® Elution Kit consists of three components; a Concentrated Wash Solution, Elution Solution and Buffering Solution intended for the acid elution of bound antibodies from intact red blood cells.

The Concentrated Wash Solution is a glycine buffered solution containing bovine serum albumin and preservative 0.85% sodium Azide. It is diluted 1 in 10 to prepare the Working Wash Solution, which is used to wash the red blood cells to remove unbound antibodies.

The Elution Solution is a low pH glycine buffer containing a pH indicator, used to dissociate the antibody-antigen complex on the red blood cells. The recovered eluate is returned to a suitable pH for serological testing by the addition of the Buffering Solution. This appearance of a blue colour indicates that the eluate has been restored to a suitable pH range for testing.

The Buffering Solution is a solution containing tris hydroxymethyl aminomethane (Trizma base), bovine serum albumin and preservative <0.1% sodium Azide.

Concentrated Wash Solution is supplied in a 30 mL Nalgene bottle, and the Elution Solution and Buffering Solution are both supplied in 10 mL glass vials with a dropper.

The Ortho® Elution Kit components are packaged in a labelled cardboard carton.

Intended Use/ Indications for Use

The Ortho® Elution Kit is intended for use in the acid elution of antibodies from intact red blood cells to allow further detection and/or identification.

The Ortho Elution Kit is an accessory for sample preparation only and does not return diagnostic results for an analyte.

Intended for professional use within a blood donor or clinical laboratory environment to perform acid elution of antibodies relating to transfusion in the general population.

Single use.

For prescription use only.

Indications for Use Comparison

The Indications for Use for the Ortho® Elution Kit are the same as for the marketed Immucor Elu-Kit II device.

Technological Comparison

The classification, intended use, composition, mode of action, and safety and effectiveness of the subject device, Ortho® Elution Kit, and the US legally marketed predicate Elu Kit -II (BK830014, are substantially equivalent.

Non-Clinical and/or Clinical Tests

As the ORTHO Elution Kit is an accessory for sample preparation only and does not return diagnostic results, clinical performance evaluation data cannot be presented as diagnostic performance characteristics such as sensitivity and specificity. As such, clinical performance is defined as the agreement of results between the Ortho® Elution Kit and the currently marketed Immucor ELU II Elution Kit.

A study was performed at one internal site in Alba Biosciences Ltd., Edinburgh, United Kingdom with testing conducted from 03 Jul 2023 to 03 Aug 2023.

Sample Stability and Anticoagulant Studies demonstrate the length of time post bleed samples can be used in the elution procedure and the length of time eluates can be tested post elution when stored at 2 to 8 °C. In addition, results demonstrate equivalent results are returned between EDTA and CPDA anticoagulants.

Reproducibility and Interoperability studies demonstrate the performance of the Ortho® Elution Kit is repeatable and reproducible.

The comparator study demonstrated equivalent performance of the Ortho® Elution Kit to that of the predicate Immucor ELU II Elution Kit.

Summary & Conclusions

The non-clinical testing and comparison to the predicate device show the subject Ortho® Elution Kit to be substantially equivalent to the predicate device.

In conclusion, the Ortho® Elution Kit is substantially equivalent to the predicate device in terms of functionality, performance, technological characteristics, and Indications for Use, including for safety and effectiveness.