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## 510(k) Summary of Safety and Effectiveness

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### Device Information

**Proprietary Name:** UltraCW  
**Common/Usual Name:** Cell Washer  
**Classification Name:** CENTRIFUGE, CELL-WASHING, AUTOMATED FOR IMMUNO-HEMATOLOGY  
**Device Classification:** Class 2  
**Regulation Number:** 21 CFR § 864.9285  
**Product Code:** KSN

### Predicate Device

**Device Name:** Centra W  
**Manufacturer:** IEC  
**510(k) Number:** BK820020

### Indications For Use

For use in immuno-hematology laboratories to automatically perform the washing phase of the anti-globulin procedure.