

K 970170

Premarket Notification (510k) Summary

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**Date:** This summary was prepared 1-1-97  
**Name of Device:** Swift Delivery Product #002  
**Common Name:** Vacuum Extractor Cup  
**Classification Panel:** OB/GYN  
**Product Code:** 85HDB  
**C.F.R. Section:** CFR - 21 (884.4340)  
**Device Class:** Class II  
**Indication Use:** Vacuum Extractor Cup used in child birth  
**Equivalence to:** K890307 Mityvac Vacuum Extractor with release valve

**Description of the Device:** The new product is an improved vacuum extractor cup. The improvement is found in the location of the vacuum tubing attachment point and vacuum release valve.

**Description of use:** This vacuum device is used in child birth to allow a physician to assist the mother in a safe vaginal delivery.

**Comparison of Mityvac and our new 002 Cup:** The cup and stem on both products are substantial equivalent. The tubing attachment locations are different. This new location will reduce cup pop-offs and increase physician comfort and control of the cup. The new vacuum release valve location and design allow easy single handed delivery and vacuum control.

**Non-Clinical Performance Data:** A survey was distributed to a select group of physicians in nine states. They indicated this improvement was needed in the vacuum delivery product.

**Conclusions drawn from non-clinical data:** The vacuum delivery products now in use can be improved. The new 002 product WILL INCREASE the SAFETY of delivery for the baby, REDUCE the AMOUNT OF TIME of delivery for the mom and provide an IMPROVED CUP for the physician.