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Premarket Notification (510k) Summary

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Date: This summary was prepared 8/15/96
Name of Device: The Tulip Cup
Common Name: Vacuum Extractor Cup
Classification Panel: OB/GYN
Product Code: 85HDB
C.F.R. Section: CFR - 21 (884.4340)
Device Class: Class 11
Indication Use: Vacuum Extractor Cup used in child birth
Equivalence to: K890307 Mityvac® Vacuum Extractor 004M

Description of the device: The new Tulip Cup is a design change to the current Mityvac® (004M) vacuum extractor cup. The change is found in the location of the vacuum tubing attachment point.

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 Tulip Cup: The cup and stem on both products are substantial equivalent. The tubing attachment locations are different.

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 products.

Conclusions drawn from non-clinical data: The vacuum delivery products now in use can be improved. The new Tulip Cup is a design modification.