



510(k) Summary

June 6, 1997

Trade Name: Umblicup
Common Name: Umbilical Cord Blood Sampling System
Classification: Empty container for the collection and processing of blood and blood components, 21 CFR §864.9100.

The Umblicup Cord Blood Sampling System that is to be marketed by Utah Medical Products, Inc. (UM), and that is the subject of this submission, is an umbilical cord blood sampling system used by delivery room clinicians to collect cord blood for laboratory analysis. The Umblicup system is substantially equivalent to the products and procedures shown in the "This Simple Procedure" video for the collection of umbilical cord blood.

The device consists of an injection molded thermoplastic body with an upper chamber for pooling the umbilical cord blood and a lower collection port that has a shrouded needle for transferring the blood to rubber stoppered collection tubes. There is a protective cap that snaps onto the collection chamber to prevent spills. There is also a protective cap on the collection port for added protection, against needle sticks, during handling.

The Umblicup is a cord blood collection device that is used in combination with items normally used in delivery rooms and is also supplied as a kit containing the required clamps, scissors, gauze pads and blood collection tubes. The device is indicated for use by delivery room clinicians for the collection of umbilical cord blood and the transfer of the blood to vacuum tubes for laboratory analysis.

The technological characteristics of the Umblicup Cord Blood Sampling System, that is the subject of this submission, are substantially equivalent to the products and procedures presently used in delivery rooms. There are differences in the dimensions of the blood collection reservoirs, however, the new device and the predicate devices are all manufactured using the same kinds of biocompatible materials.

Tests of the Umblicup System have demonstrated that it is a safe and easy to use system for the collection of umbilical cord blood.

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