



K 955663

SMDA 510(k) Summary

MAR 17 1997

Appendix A

Trade Name: ABC In-Line Blood Sampling Kit
 Common Name: In-Line Blood Sampling Device
 Classification: Continuous Flush Catheter. 21 CFR §807.92.

The ABC ("Arterial Blood Collection") In-Line Blood Sampling Kit is a closed blood sampling system used in conjunction with continuous blood pressure monitoring in a critical care setting. The ABC Kit is designed for use with all disposable and reusable pressure transducers and for connection to central line catheters and arterial catheters. The ABC Kit is used for the drawing and retention within the line of heparinized blood from the catheter/cannula, allowing undiluted blood samples to be drawn from an in-line sampling site. At the completion of sample drawing, the mixed heparin/blood solution is reinfused into the patient to reduce fluid loss.

The device is substantially equivalent to the Baxter VAMP™ blood sampling system cleared for marketing under 510(k) K/885281. Although the ABC blood collection reservoir is of a different shape and larger capacity compared to the VAMP reservoir, the frequency response of the system in pressure monitoring is essentially equivalent.

→ see also draw safe K885235

Materials used that contact IV fluids and blood are equivalent to materials of the VAMP system. Biocompatibility and sterilization information is available from Utah Medical Products, Inc. upon request.

Kevin L. Cornwell
 President & CEO

Biocompatibility
and Sterility