SUMMARY OF SAFETY AND EFFICACY

A. The submitter's name, address, telephone number, contact person, and date of preparation.

   Submitted by Becton Dickinson Vascular Access, 9450 South State Street, Sandy, UT 84070. Contact: C. J. Welle. Telephone: 801-565-2535. Prepared: October 8, 1996.

B. The name of the device including trade or proprietary name if applicable, the common or usual name, and the classification name.

   Name: Midline Catheter Kit
   Brand: FIRST MIDLINE™
   Common Name: Midline Catheter Kit
   Classification Name: None. The catheter component is classified as a Long Term Intravascular Catheter (80 LJS)

C. An identification of the predicate or legally marketed device to which substantial equivalence is claimed:

   Predicate Device: The Becton Dickinson Vascular Access FIRST PICC™ brand kit.

D. A description of the device that is the subject of the Premarket Notification submission.

   The subject kit contains a long term, single use, single or dual lumen, intravascular catheter of various French sizes and lengths which is designed to provide access to large veins such as the baslic or cephalic veins. It also contains drugs and devices for preparing the insertion site, placing the catheter, securing the catheter and dressing the site.

E. Statement of intended use of the device.

   The kit contains a midline catheter suitable to sample blood or administer drug solutions, blood products, or other fluids intravenously. Other components are used in the course of placing the catheter as indicated above.

F. A statement of how the technological characteristics compare to those of the predicate or legally marketed device identified in section C above.

   The proposed kit differs from the FIRST PICC™ brand kit in that the FIRST MIDLINE™catheter is shorter than the FIRST PICC™ catheter; however, the materials used, the design concept, the manner in which the catheter is placed, and designation as a long term catheter are the same. Other componentry varies to meet customer needs.