

K970259
April 8, 1997

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: January 22, 1997

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

Name: Intravascular Administration Set

Brand: E-Z SET® and Saf-T E-Z SET® Infusion Sets

Common Name: Infusion Set

Classification Name: Intravascular Administration Set (80 FPA)

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

Predicate Device: The Becton Dickinson Vascular Access E-Z SET® and SAF-T E-Z SET® brand infusion sets.

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

The subject catheter is a single use intravascular administration set of various gauges and lengths which is designed to provide access to the vascular system. It is stainless steel needle set with butterfly wings and a short extension set.

- E. Statement of intended use of the device.

The intended use is to provide access to the vascular system to administer fluids intravenously. The device is also suitable for sampling blood and monitoring blood pressure.

- 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 infusion sets differ from the E-Z SET® and SAF-T E-Z SET® brand infusion sets currently marketed in that the intended use clarifies the suitability for additional uses. The device is unchanged.