

K970255

## PREMARKET NOTIFICATION SUMMARY

APR 14 1997

**Classification Name:** Set, Administration, Intravascular  
**Common Name:** I.V. Manifold  
**Trade Name:** KippMed I.V. Manifold  
**Predicate Device:**

The predicate device is marketed B. Braun Medical Inc. and is named the Safesite - Anesthesia Tripple Valve Manifold; #AET-3000; 510(k) K942391.

### **Device Description:**

The KippMed I.V. Manifold is substantially equivalent to the Braun Safesite Manifold. Minor differences in design specifications have been listed in Table One. Both devices are intended to provide connections to an I.V. Administration Set. Both devices provide a multi-port connector with a female leur-lock adapter, three normally closed backcheck valves and a connection adapter. The inlet connection adapter for both devices includes a free-spinning hub/leur lock to connect to I.V. lines. Both devices are sterile and nonpyrogenic.

### **Intended Use:**

This device is intended to be used as a conduit for the delivery of I.V. fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. Additionally, this device is intended to serve as an injection site for other infusion fluids. This device is intended to be used only by trained professionals in a clinical or hospital environment.

### **Comparison of Technical Characteristics to Predicate Device(s):**

Table 1, included on the last page of this summary, provides a comparison of the technological characteristics of the KippMed device to the Braun Safesite.

**Sterilization:**

The KippMed manifold is sterilized by Gamma radiation. The sterilization process has been validated to provide a SAL of  $10^{-6}$ .

**Biocompatibility:**

Biocompatibility for the components used in the KippMed device have been tested in accordance with ISO 10993 and FDA General Program Memorandum G95-1. Tested components were subjected to the maximum number of sterilization cycles specified in the Device Master Record. All tested components were biocompatible.

**Reviewed and Approved By (Contact Person):**



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