

K962081

NOV 1 1986 SUMMARY OF SAFETY AND EFFICACY

The proposed kit raises no new issues of safety or efficacy. In incorporating the components into a kit no modifications have been made which will affect safety or efficacy. Sterilization method and packaging are essentially the same.

The I.V. sets and transducer protectors are legally marketed as individual components. The arterial and venous bloodlines are substantially equivalent to legally marketed bloodlines. These bloodlines have been functionally tested and data provided. The blood contact materials of the arterial and venous bloodlines have been tested for biocompatibility and data provided.

The integrity of the bonded connections of the bloodlines and of the connection of the transducer protectors to the monitor lines have been tested and data provided.

No new claims or indications are made.