

K960280

APR - 4 1996

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

- 1. **SUBMITTER'S NAME:** IVAC CORPORATION
10300 Campus Point Drive
San Diego, CA 92121-1579
(619) 458-7825

- CONTACT PERSON:** Jennifer S. Hankard
Sr. Manager of QA/RA

- DATE PREPARED:** January 17, 1996

- 2. **DEVICE NAME:** Proprietary Name: IVAC Needle Free Valve Administration Sets

Common Name: Intravascular Administration Set

Classification Name: Intravascular Administration Set

- 3. **PREDICATE DEVICE:** ICU Medical, Inc. Clave Connector

- 4. **DEVICE DESCRIPTION:** The IVAC Needle Free Valve administration sets incorporate standard IVAC set components using standard materials. The sets include a needle free valve that allows the user to add medication into the primary line without the use of a needle. When the valve is in the closed position it has a flat smooth surface for cleaning. When the male connector of a syringe or secondary line is pushed into the valve the rubber piston inside the valve is compressed. The top of the rubber piston is then allowed to expand into the increased diameter inside the valve. Fluid path is achieved through the male connector into the center of the rubber piston and the valve housing. When the male connector is removed from the valve, the bellows section of the piston provides a spring force to return the piston to the top of the valve and to maintain a sealed fluid path. A cap is not required to maintain sterility.

- 5. **INTENDED USE:** The intended use for the IVAC Needle Free Valve administration sets is to allow IV fluid delivery of a wide range of fluids. The needle free valve allows the user to add medication into the primary line without the use of a needle.

6. TECHNOLOGICAL CHARACTERISTICS:

The IVAC Needle Free Valve administration sets and the ICU Medical, Inc. Clave Connector use the same method of manufacture, incorporate standard set components, and use standard materials. The primary function of the IVAC Needle Free Valve administration sets is the same as the ICU Medical, Inc. Clave Connector: to allow the user to add medication into the primary line without the use of a needle. The technological characteristics of the devices are the same and raise no new questions of safety and effectiveness. IVAC Corporation concludes that the IVAC Needle Free Valve administration sets are substantially equivalent to the ICU Medical, Inc. Clave Connector.