

APR 21 1997

K970485

SmartSite™ Access Pin  
510(k) Premarket Notification

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:** IVAC Holdings, Inc.  
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**CONTACT PERSON:** Renée L. Fluet  
Regulatory Affairs Specialist  
  
**DATE PREPARED:** February 7, 1997
2. **DEVICE NAME:** *Proprietary Name:* SmartSite™ Access Pin  
  
*Common Names:*  
(1) Intravascular Administration Set  
(2) Transfer Set  
  
*Classification Names:*  
(1) Intravascular Administration Set  
(2) I.V. Fluid Transfer Set
3. **PREDICATE DEVICE(S):** IVAC Needle Free Valve Administration Set, K960280  
  
ICU Medical, Inc., Piggy Lock Needle Housing, K910546.  
  
Acacia, Inc., Luer Lock Transfer Pin, K901063.
4. **DEVICE DESCRIPTION:** The SmartSite Access Pin is a stand alone accessory and is the same device as the currently marketed IVAC Needle Free Valve (K960280) with the exception of a modified housing. The housing for the SmartSite Access Pin has been modified to accommodate the needs of an access pin by adding a protected spike and finger grips.  
  
Functionally, the SmartSite Access Pin is the same as the currently marketed IVAC Needle Free Valve in that it allows access to IV administration sets. As an access pin device, the SmartSite Access Pin also allows access to medication vials, blood tubes, and solution bags without the use of needles or blunt cannulas.

5. **INTENDED USE:** The intended use for the SmartSite Access Pin is to allow access to IV administration sets, medication vials, blood tubes, and solution bags with one convenient device without the use of needles or blunt cannulas.

6. **TECHNOLOGICAL CHARACTERISTICS:** The SmartSite Access Pin consists of components which use the same method of manufacture and use similar standard materials as the currently marketed *IVAC Needle Free Valve, K960280*. The primary function of the SmartSite Access Pin is also the same as the *Needle Free Valve* with the addition of an Access Pin application which is substantially equivalent to the ICU Medical Inc., Piggy Lock Needle Housing (K910546). In addition, the SmartSite Access Pin acts as a transfer pin and is substantially equivalent to the Acacia, Inc., Luer Lock Transfer Pin (K901063)

The SmartSite Access Pin allows easy finger grip access to IV administration sets, medication vials, blood tubes, and solution bags, without the use of needles or blunt cannulas. The technological characteristics of the device are the same as the *IVAC Needle Free Valve (K960280)*, ICU Medical, Piggy Lock Needle Housing (K910546), and the Acacia, Inc., Luer Lock Transfer Pin (K901063) and raises no new questions of safety and effectiveness. IVAC concludes that the SmartSite Access Pin is substantially equivalent to the currently marketed *IVAC Needle Free Valve (K960280)*, the ICU Medical Inc. Piggy Lock Needle Housing (K910546), and the Acacia Inc., Luer Lock Transfer Pin (K901063).