

**510(k) SUMMARY**

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InterLink® Adapter for Conventional Y-Site

K962893

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**Proposed Device:**

InterLink® Adapter for Conventional Y-Site

**Predicate Devices:**

Locking Needle Sheath with InterLink® Injection Site  
InterLink® Universal Vial Adapter

**Proposed Device Description:**

The proposed InterLink® Adapter for Conventional Y-Site is designed to convert a conventional (needle-accessed) y-injection site to an InterLink® injection site (needleless access). The InterLink® injection site is incorporated into the top of the adapter to allow access to conventional injection sites with InterLink® cannulae. The adapter contains a plastic spike to pierce the conventional Y-site septum and a slot which connects to the arm of the Y-site. There are no new materials involved in the proposed adapter. All plastic and rubber materials used have been previously tested and used in other Baxter devices for similar I.V. solution administration applications.

**Statement of Intended Use:**

The proposed adapter will be used to convert a conventional needle-accessed y-injection site on a Baxter or competitive solution administration set to an InterLink® injection site. This device, like other products containing the InterLink® injection site is designed to reduce the risk of accidental needle sticks when used in conjunction with the InterLink® cannula, as part of a "needleless" IV access system.

## **Summary of Technological Characteristics of New Device to Predicate Devices**

The proposed InterLink® Adapter for Conventional Y-Site is similar to Baxter's Locking Needle Sheath (NeedleLock) with InterLink® Injection Site previously found substantially equivalent under K914048. Both products incorporate the Interlink® injection site into the top of the device to allow access to conventional injection sites with InterLink® cannulae. Both devices have a means for piercing the conventional y-site septum and both have a slot which connects to the arm of the Y-site.

The NeedleLock with InterLink® Injection Site consists of independent NeedleLock and injection site components bonded together. The proposed adapter differs in that the InterLink® injection site is integrated into the housing which results in a more compact component. The adapter contains a plastic spike to pierce the y-site septum whereas the NeedleLock device has a needle for septum penetration. The slot of the NeedleLock is L-shaped and is twisted to lock onto the y-arm. The adapter has a U-shaped slot which is positioned over the y-arm after spike penetration.

The proposed InterLink® Adapter for Conventional Y-Site is also similar to the InterLink® Universal Vial Adapter, covered by K924064. Both adapters incorporate the InterLink® injection site and allow standard needle-accessed components (Y-sites or vial stoppers) to be accessible with the InterLink® blunt cannula. Both adapters use a spike to pierce the Y-site or vial stopper which remains fully seated and secure after penetration without use of a locking mechanism.

## **Discussion of NonClinical Tests and Referenced Studies Reported in Published Literature**

Data regarding the functional performance of the proposed adapter have been generated. A description of the functional testing along with test results is provided. Testing was performed with Baxter and competitive sets including Abbott, IMED, IVAC, Burron Medical and McGaw sets. Studies evaluated the integrity of the seal between the adapter and set Y-Site and the security of the adapter on the Y-Site. The data indicate that the proposed adapter meets or exceeds all functional requirements and support its suitability for use with the intended sets.