



**Critical
Device
Corporation**

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510(k) Summary

1. Submitter: **Critical Device Corporation**
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2. Contact: Dan Hyun, President
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3. Date prepared: December 5, 1996
4. Device trade name: NIMA™ Needleless Injectionsite Master Adapter with PosiFlow™ Positive Displacement Feature, and IV Sets

Common name: Intravenous (IV) Medication Connector, and IV Sets
5. Predicate device: NIMA™ Needleless Injectionsite Master Adapter with PosiFlow™ Positive Displacement Feature, and IV Sets
6. Description: The NIMA™ adapter is a two-way valve that permits easy needleless intermittent and continuous access in IV therapy. It can be connected to peripheral or central venous catheters or Y-sites. The normally closed NIMA™ adapter valve is opened by inserting a standard male luer taper, such as on an extension set, IV tubing or syringe to the female end of the NIMA™ adapter.

This device does not require the use of hypodermic needles for the infusion of IV solutions. Thus preventing needle stick injuries. The NIMA™ adapter is packaged individually and as attached as part of extension sets
7. Intended Use:
 - a. For use as a needleless alternative to IV set injection ports. The NIMA™ adapter will replace the conventional Y-site on a primary IV line as a continuous or intermittent connection.
 - b. For use as part of a program to reduce needle stick injuries and the associated transmission of blood borne pathogens such as HIV and HBV.

- c. For use as a replacement to the injection cap (heparin cap) on an I. V. catheter for intermittent injections.
- d. For use for injection, as a gravity flow connector, and as an access port for withdrawal of fluids.
- e. For use with standard luer taper connections.
- f. For single patient use.

8. Technological comparison to predicate device:

The NIMA™ adapter with PosiFlow™ feature compensates for the displaced volume due to the adapter seal closing when the proximal (up line, or away from the patient) standard luer connection is removed. This feature is expected to be most effective in very small bore peripheral vascular access devices which are filled with a heparin flush to keep the access patent. Blood retrograde is one of the factors associated with clot formation and potential occlusion of catheters and cannulas. The PosiFlow™ feature is designed to compensate for blood retrograde into the vascular access device as a result of disconnecting a fluid source from the NIMA™ adapter.

The performance of the NIMA™ adapter in microbial challenge is centered on the design and configuration of the reseal septum. Neither the material nor the design of the reseal septum is changed from the predicate design.

The proposed change does not require any procedural changes by the user.

9. Nonclinical test summary:

The new design meets all performance specifications established for the originally approved device. Tripartite biocompatibility testing indicates that the new materials are safe and biocompatible.

10. Conclusion:

The NIMA™ adapter with PosiFlow™ Positive Displacement Feature modification(s) have demonstrated safety and effectiveness, and is substantially equivalent to the legally marketed predicate device.