Critical Device Corporation
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510(k) Summary

1.	Submitter:	**Critical Device Corporation** 499 Nibus Street Brea, CA 92821 Tel: 714-257-2197 or 800-321-6462 Fax: 800-299-4849
2.	Contact:	Dan Hyun, President Critical Device Corporation
3.	Date prepared:	November 22, 1996
4.	Device trade name:	NIMA™ Needleless Injectionsite Master Adapter and IV Sets
	Common name:	Intravenous (IV) Medication Connector and IV Sets
5.	Predicate device:	NIMA™ Needleless Injectionsite Master Adapter 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.

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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 technological characteristics are equivalent to the currently approved NIMA™ Needleless Injectionsite Master Adapter and IV Sets. Alternate materials and use duration extended from 24 to 96 hours are approved in this application.

9. Nonclinical test summary:
New materials meet 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™ modification(s) have demonstrated safety and effectiveness, and is substantially equivalent to the legally marketed predicate device.