K970359

II 510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

B. Braun Medical, Inc
824 Twelfth Avenue
Bethlehem, PA 18018
(610)691-5400

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Contact: Mark S. Alsberge, Regulatory Affairs Manager

Product Name: CombiPort Emergency Infusion Device

Trade Name: **I.V. Fluid Transfer Set**

Classification name:

Hospital
Class II, 80LHI
21 CFR 880.5440

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K925401	IV Fluid Transfer Pin	B. Braun Medical Inc.

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce The CombiPort Emergency Infusion Device. This device is equivalent to an IV set and is utilized to transfer fluids from a container to a patient's intravascular access catheter. The device offers the capability of high flow rates which may be desirable in emergency trauma treatment.

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[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not

applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

Material:

The CombiPort Emergency Infusion Device is composed of materials that have been tested in accordance with the ISO Standard 10993 and have been determined to be suitable for the intended use of this product.

Substantial equivalence:

The CombiPort Emergency Infusion Device is similar in materials, form, and intended use to I.V. Fluid Transfer Pin cleared by B. Braun Medical Inc. There are no new issues of safety or effectiveness raised by The Emergency Infusion Device.

Safety And Effectiveness:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.