

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

K955179

B. Braun Medical, Inc

MAR 12 1997

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PRODUCT NAME: Contrast Media Set

TRADE NAME: Intravascular I.V. Administration Set

CLASSIFICATION NAME:

General Hospital  
Class II, 80 FPA, Intravascular IV Administration Set  
21 CFR 880.5440

SUBSTANTIAL EQUIVALENCE<sup>1</sup> TO:

510(k) number	Name	Applicant
K915678	Administration Set	Merit Medical
K943181	Dispensing Pin W/One Way Valve	B. Braun of America
K903493B	Contrast Savings Delivery System	NAMIC

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 Contrast Media Set. The Contrast Media Set is for reducing contrast waste by allowing one bottle of contrast to be used on more than one patient.

<sup>1</sup> 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 Contrast Media Set is composed of materials that have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

*Now ISO*

**SUBSTANTIAL EQUIVALENCE:**

The Contrast Media Set is equivalent in materials, form, and intended use to Contrast Management Systems currently marketed by Merit Medical and NAMIC. There are no new issues of safety or effectiveness raised by the Contrast Media Set.

**SAFETY AND EFFECTIVENESS:**

*Merit Medical does not claim  
Multiple use in their 510k's.*

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.